UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, And WISCONSIN, *ex rel.* CATHLEEN FORNEY,	
Plaintiffs/Relator,	
vs.	
MEDTRONIC, INC.,	
Defendant.	
	Case No. 5:15-CV-06264-EGS
	601 Market Street, Philadelphia, PA 19106
	Wednesday, December 20, 2017

TRANSCRIPT OF MOTION FOR SUMMARY JUDGMENT
BEFORE THE HONORABLE EDWARD G. SMITH, U.S.D.J.
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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(Appearances Continued)

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(Proceedings commence at 9:59 a.m.)

(Call to order of the Court)

THE COURT: Good morning, Counsel.

COUNSEL: Good morning. Good morning, Your Honor.

THE COURT: Please be seated. Thank you.

The Court is called to order in the matter of the United States of America, and in particular Cathleen Forney v. Medtronic, Inc. This is Civil Action Number 15-6264.

The Court convenes today to hear argument with respect to the defendant's motion for summary judgment, based on the public disclosure bar. The defendant claims that the public disclosure bar does apply in this case. Obviously, the plaintiff -- the defendant claims that; the plaintiff, obviously, disagrees.

Counselor, are you ready to argue on why I should throw this case out, based on the public disclosure bar?

MS. MAYER: Thank you, Your Honor.

THE COURT: Certainly. And you may argue wherever you're most comfortable.

MS. MAYER: Thank you.

I'd like to start just by talking very briefly, by way of introduction, about the prior-filed *qui tam* complaints, and then I'll jump right into the initial set of arguments, which is the discussion of why these prior-filed *qui tam* complaints constitute public disclosures under the

False Claims Act's public disclosure bar.

Over the course of about three years, four years, a series of False Claims Act complaints came out from under seal. And in each of those complaints, the Relator in the case, which was a former Medtronic employee, made allegations. Some of those allegations are entirely focused on the same theories that Ms. Forney is alleging in her complaint. Some of them are focused on other theories, but include theories that Ms. Forney has alleged in her complaint.

And one of them in particular, the Stokes case, which we'll talk a little more about later, has a different legal theory and a lot of facts in support of that theory that is not in Ms. Forney's case, but, along the way and necessary to that theory, alleges facts that are very pertinent to, and disclose pertinent facts relating to the allegations in Ms. Forney's complaint. And I'll tie that together in a minute.

What I wanted to say, by way of introduction, is introduce you a little bit to the Relators in these cases because Ms. Forney's brief emphasizes that Ms. Forney is a long-time employee of Medtronic before she left her employment; that, as a result, she is not the kind of relator that the statute intends to bar, and that that's a fact that's germane to the analysis that the Court is going to go

through today.

I wanted to talk just briefly about the relators in these other complaints, both to balance the record on this, and to point out that, in fact, whether the relator was a long-time employee or not is not relevant. There is one relevant question that Ms. Forney's experience can speak to, which is: Does she have independent information that she disclosed to the Government in advance of filing her action that materially adds to the action? On that point, she's entitled to, and she has, through declarations, stated that the information she supplied was not based on the prior-filed *qui tam* complaints, and that she had not seen them.

Other than that statement, all of the color about her tenure at Medtronic, the different positions she held, and the extent of the information she gathered from the company during that time is literally irrelevant and actually cannot be considered for purposes of evaluating the public disclosure bar.

But for starters, I also wanted to point out that Ms. Forney is not unusual in being a former employee, bringing a case, and having personal and important information to share with the Government, from her perspective.

In the Burns case, the relator was a ten-year employee of Medtronic when the amended complaint was filed.

He had been a sales representative in the Cardiac Rhythm Business Unit, which is the business unit where the device checks are at issue in this case. And he makes allegations about free device checks used as a kickback in Florida and North Carolina, with a great deal of specificity, including providing examples of superbills and physician practices that he alleges were the recipients of these kickbacks, and participated in the scheme.

The Onwezen and Brill -- it's the Onwezen, et al complaint, which we refer to as the "Onwezen Complaint" in our papers, had three relators. It sued multiple defendants, including Medtronic, in the industry. And two of the relators were Medtronic employees. Onwezen herself was a clinical specialist, so, again, the exact type of person that allegedly, at Medtronic, their job is to provide free device checks and interrogations, day in and day out, to everybody who needs one for a Medtronic device. And she was employed in that role for three years, and said that's what she did.

Brill was employed for ten years as a field engineer, which is another type of field support role in Medtronic, in its business unit, and then was promoted to principal field engineer. And between Onwezen and Brill, they cover Missouri and Massachusetts. Those are where they worked, but their allegations go broader than that.

In the Stokes complaint, the relator was a senior

manager of healthcare economics. He did -- personally developed economic tools and resources for Medtronic to use in this Cardiac Rhythm Unit. He visited and worked with over 300 hospitals across 40 states, teaching them about documentation practices, coding, and billing for devices.

And he alleges in his complaint -- this is the one where his legal theory is very different from Ms. Forney's. But he alleges in his complaint that Medtronic reps were trained to and providing -- Medtronic field personnel -- and providing device checks, programming devices and interrogations nationwide, and that -- and then he goes on.

He actually had gotten MedPAR data and analyzes clusters of what he alleges are statistically significant outliers in 18 different regions of the country, identifying multiple hospitals in those regions, where he says there was an overuse of the theory in the case, which was that the reps were programming these devices during their checks and during their -- what was service they were providing in doctors' offices, that they were programming the devices to expire quickly, so that there would be a need to ex-clamp them and put a new one in quickly. So, again, the legal theory is different, but the necessary allegation of the theory is that Medtronic employees were controlling these checks and programming events, and were doing them all the time. And there's a lot of specificity about where that was happening.

And then, in the Schumacher complaint (phonetic), he was a short-term employee, only for one year, at Medtronic. But he was a business development manager, so, yet again, another type of position within the organization, adding color to the allegations. He certainly alleged theories of off-label promotion and kickbacks in the form of cash payments, relating to clinical trials and research. But he also, very specifically, alleges that the kind of reimbursement and other business consulting that is very much a part of Ms. Forney's theory was being used as a kickback, as well, during that time frame, and he has some specific examples related to that in his complaint.

So, collectively, these four complaints -- and I'm focusing on the Medtronic ones for now, at this introductory stage -- you know, cover almost 25 years or more of employment at Medtronic, across a range of positions, a range of geographies; Florida, you know, District of Columbia, California, Missouri, Massachusetts. They have varying degrees of specific examples of the kind of misconduct that's at issue in Ms. Forney's case. And they all allege substantially the same theories that Ms. Forney is now pursuing.

So I'm going to turn then to the question of whether these *qui tam* complaints are the kinds of documents that qualify as a public disclosure under the False Claims

Act because we didn't focus on that in our opening brief because it's really not something that's contested in the case law ever. And we believe that, under the plain language of the statute and Supreme Court precedent that goes back almost two decades, it's really not something that's in dispute. So let -- we can talk about that.

Before we do, I did want to just, again, mention that, for purposes of argument and the briefing, as we noted in the reply, that Ms. Forney has narrowed her case a little bit to focus on only conduct that resulted -- that occurred on or after March 23rd, 2010, so that the current --

THE COURT: Put it in the --

MS. MAYER: -- version --

THE COURT: -- post-amendment --

MS. MAYER: -- of the post-amendment --

THE COURT: So there's no --

MS. MAYER: -- version of the --

THE COURT: -- pre-amendment --

MS. MAYER: -- bar applies.

THE COURT: No pre-amendment allegations in this case. Okay.

MS. MAYER: And then, second, that Ms. Forney is not pursuing any claims based on the theory that kickbacks associated with implant procedures remain a part of the case. That was something that was part of her allegations in the

complaint, and we addressed it in our opening brief. But Ms. Burke has confirmed that she is limiting the theories that she is proceeding on and defending here to the device checks and the kickback and the practice management, consulting services aspects.

THE COURT: All right. Now I want to get this quick. So it would be no conduct prior to March 10 of 2010?

MS. MAYER: March 23rd of 2010.

THE COURT: March 23rd of 2010. So we no longer have to dual distinction between pre and post.

MS. MAYER: Right.

THE COURT: And the theory now is limited to the device checks, where somebody goes back, and Medtronic does a device check, as opposed to the implants. How do we describe that?

MS. BURKE: Yes, Your Honor. It's limited to the device checks. But then, in addition, the practice management consulting, which subsumes the -- what the defendant has labeled "administrative work" and "reimbursement." Those are all a part of what we label the "practice management consulting."

THE COURT: Okay. But not the implant -- is it the implant -- you check on the implant, that part?

MS. BURKE: Your Honor, the Medtronic clinical specialists and sales reps attend the surgical implants and

are there to assist in interrogating the device at the actual implant surgery. For purposes of limiting the trial and avoiding jury confusion, we've decided to go with what we call the "device checks," which are well after surgery, and are clinics run, in which the patients come back and simply get the device checked.

THE COURT: Okay. So all implant assistance, at the time the implant is being inserted, those are being withdrawn.

MS. BURKE: That's right. We are not pursuing that theory of liability at trial.

THE COURT: It's after they are out of the operating room, now they're -- it's post-operative, and they go back for a check, those are what the claim is, that that's the kickback.

MS. BURKE: Yes, Your Honor.

THE COURT: Okay. Thank you.

Counselor, excuse my interruption.

MS. MAYER: So I think where we start, with the question of whether the complaint qualifies as a public disclosure is with the statute. And the statute -- and I don’t think there's any dispute about what the post-PPACA public disclosure bar says about what types of documents qualify as a public disclosure. But for our relevant purposes, the provision is 3730(e)(4)(A)(i), which is that

it's disclosed in a federal criminal, civil, or administrative hearing, in which the Government or its agent is a party. So the question is: Are these complaints disclosures in a federal civil hearing, in which the Government or its agent is a party?

And Ms. Burke has challenged a couple of different pieces of that. First, she argues in her brief that, in fact, what Moore, a Third Circuit case from, I think, 2016 -- it's either 2016 or early this year, but it's recent -- interpreting the public disclosure bar, she argues that Moore holds that what that statute means is not Government or its agent, but just Government. Okay? And then she takes that to be a holding in the case, and argues from there.

We addressed this in our reply brief, but I think it's critical, when looking just at the language of the statute and at Moore, to recognize that, in Moore -- again, our view is the Court, when you read the decision properly, is not holding, and cannot be viewed as holding that this statutory provision does not mean what it says when it says "or its agent;" that Moore was just sort of referring to that language in shorthand because Provision (i) here was not even a little bit at issue in the appeal, and so there was no need for the Court to be fulsome with its quote from the statute, when it was referring to it.

The only public disclosures at issue in Moore were

a FOIA report, which is -- the Court discussed whether it qualifies as a public disclosure under (ii), and news media, which qualifies as a public disclosure under (iii). So, for starters, the Court wasn't actually -- didn't have before it any question about whether anything constituted a public disclosure under (i), let alone whether a particular document should be viewed as qualifying, when the Government was not a party.

In the District Court -- and this is where I think some confusion comes into, in some of these cases. In addition to the tendency to speak in shorthand, in the District Court, because claims bridged the PPACA amendment. There was a claim, which didn't end up getting appealed, that the defendant made, that the information that the relator brought to the case was discovery that the relator had secured by litigating a wrongful death action, a couple of wrongful death actions, in Federal Court; and that, therefore, the discovery, which qualifies as documents as -- that were disclosed in a federal civil hearing under the old statute, qualified as a public disclosure, and served as a bar under the old PPACA.

And so those were private party litigation, as opposed to litigation where the Government is a party, meaning that it's the widow, who is the plaintiff, suing, you know, the company defendant, and trying to get redress for a

wrongful death. It's a tort claim. It's not a case where the plaintiff is a relator, who's a statutorily designated agent of a government.

And so the District Court referred to the requirements under the new statute as a requirement that the Government be a party to the litigation, as a shorthand way of distinguishing cases where, you know, you've got a tort claim between a private citizen and another private citizen, and nobody is an agent of the Government. So there is no analysis of the District Court in the briefs or in the Third Circuit about whether an agent of the Government is somehow excluded from the plain language of this amended statute. So --

THE COURT: It almost seems like they use -- the public disclosure has been interpreted as public disclosure, such that the Government is aware of this conduct, as much as that the public is aware of this conduct.

MS. MAYER: I think it is -- it's not a -- there isn't an obligation, when you're evaluating whether something qualifies as a public disclosure, to determine that the Government was aware of it --

THE COURT: But they were --

MS. MAYER: -- in addition --

THE COURT: -- a party to --

MS. MAYER: -- to evaluating.

THE COURT: -- the suit.

MS. MAYER: And the reason why I just mention that, for clarity's sake and to be candid with the Court, is the news media, you know, bucket, there are documents that qualify as news media that no one would suggest that DOJ lawyer would notice in passing.

And the Moore case is a great example because one of the news media reports was from the Vashon Beachcomber, and just because I'm a nerd on this stuff, I had to look up what that was. And it's a local newspaper for an island in Puget Sound. It's -- you know, it would be like the functional equivalent of some sort of local hometown weekly from, you know, a small town around Easton.

THE COURT: Right.

MS. MAYER: We have something equivalent in the town I live in, in Massachusetts, where the feature articles are -- sometimes have a lacrosse team bid, and you know, the pictures of the six-year-olds, you know, donating to the --

THE COURT: Right.

MS. MAYER: -- local animal shelter. This is not a big circulation paper, but it's news media, even though the Government doesn't know about.

Here, I think, in particular, there's no need to take an unduly limiting -- well, aside from the fact that Third Circuit, under Moore, simply didn't hold that agent is

excluded from the statute here, and nor could they because it's the plain language of the statute. It would make no sense because -- especially for purposes of False Claims Act complaints. Although the Government may eventually decline to intervene, when the relator brings the action, in the first instance, they all start the same way, which is by filing -- which is by providing the Government all your information that you want to rely on in the case, and then filing the complaint under seal, and serving it on the Government.

So, literally, by statutory definition, every single False Claims Act complaint is not just something the Government might happen on, if they're paying attention to the news in Puget Sound. But it is a piece of litigation that is served on the Government, and that then triggers, on the part of the Government, some obligations to review the information, to investigate it, to advise the Court within 60 days whether it was going to intervene, or seek an extension of that time.

And so, for purposes -- to the extent that, I think, Congress -- again, and I don't want to overemphasize the importance of legislative history here, especially where there really isn't any of these particular changes to the False Claims Act. But as a general directional matter, the balance that we try to strike, and that Congress has tried to

strike over the years with the public disclosure bar, again, just directionally, is to allow suits to proceed, where the relator is bringing new information that could really be materially helpful to the Government in rooting out fraud. Those should be allowed to proceed, even if the Government doesn't intervene and take over the case, but that there's got to be some recognition that you can't just keep, you know, pinging the Government *ad infinitum* on the same theory, over and over again.

At some point, if you're not bringing anything new to the table, whether you're parasitic or not, even if it's all your own information, if you're really not bringing anything new to the table, and they've already looked at it before, and they've been to this dance --

THE COURT: But I thought --

MS. MAYER: -- if they don't intervene, it can have --

THE COURT: I thought the theories in this case were somewhat novel.

MS. MAYER: So --

THE COURT: And that kind of goes against this whole idea that there might be a public disclosure bar.

MS. MAYER: They're novel in the case law, they're novel -- it's not -- and I -- I mean, I'm happy to represent to the Court I was not aware of the prior-filed *qui tams* when

we were litigating the motion to dismiss. It doesn't change the fact that, under the case law, you do not see cases litigating these issues.

And I think, critically, what you also don't see is, after five complaints, the Department of Justice stepping in and asserting that it believes that this conduct violates the law. Now you can't -- I mean, they can decline to intervene for any reason at all, and so I don't want to suggest that that's a reason to infer that, under the law, that there's any legal consequence to that. But what it goes to is that, as a practical matter, these issues have never been teed up to a court to resolve, as to whether this is an anti-kickback statute, and for what --

THE COURT: Could that be for the very reasons set forth in your motion to dismiss, originally?

MS. MAYER: That these are not remuneration under the anti-kickback statute? Yes, absolutely. I -- you know, again, I don't -- at this stage, on this record, I can't make representations about what was or wasn't in the mind of the lawyers at the Department of Justice, when they investigated claims coming out of this prior-filed complaints, and ultimately chose to pursue some claims in a couple of the complaints, but none of the claims that overlap with Ms. Forney's allegations. And I don't think the Court can base a decision, based on the Department of Justice's decision not

to act. But yeah, I think, you know, certainly, should the case proceed, that's all relevant information to any potential sort of merits resolution of the issues.

Here, what's critical under the False Claims Act, for purposes of evaluating whether these prior-filed civil *qui tam* complaints can qualify as public disclosures is that, in the first instance, Moore, because it is the Third Circuit, certainly has not held that, for purposes of (b)(4)(A)(i) that disclosures are limited to disclosures in a hearing in which the Government, to the exclusion of its agent, is a party. So agent is in the mix.

The next question is: Well, is the relator an agent of the Government, for purposes of the False Claims Act? And the answer there is in the Vermont Agency of Natural Resources v. Stevens case that we cited. It's the Supreme Court.

In that case, which was addressing the article -- the question of whether relators have Article III standing, and it resolved it. So you don't actually see this case cited a whole lot. There was a little flurry afterwards, but then it kind of died out because, at some levels, some issues get decided, and then you go forward.

In this case, the -- there are two main legal issues, and it's the first one addressing standing that I want to point the Court to, and we have the cites in our

brief. But here -- this is at -- and I'm trying to get that other case out here.

But here, Justice Scalia, writing for the majority, you know, starts talking about what might provide a basis for Article 3 standing here. And he recognizes that Stevens, the relator here, contends he's suing to remedy an injury, in fact, suffered by the United States. So the first step is the injury, in fact, at issue in these cases is an injury suffered by the United States. And so Scalia says:

> "It would perhaps suffice to say that the relator here is simply the statutorily designated agent of the United States, in whose name, as the statute provides, the suit is brought, and that the relator's bounty is simply the fee he receives out of the United States' recovery for filing and/or prosecuting a successful action on behalf of the Government."

So the first step is to say, you know, well, under the statute, he's a statutorily designated agent, and so many that's enough here. The Court then, of course, famously says:

> "But that doesn't fully explain the personal interest that the relator has in the bounty."

And so that what we have here -- and I'll go through the different pieces because this is a nuance in the

case that sometimes gets lost when it's summarized in the lower courts later on, and they focus on the rationale for standing over the bounty, is that, for the piece where the Government retains an interest, Scalia has said -- and this never changes through the opinion -- this is representational standing, and the Government remains the real party-in-interest to the case. This is a concept that's familiar in the law, and not unique to the False Claims Act. The Government can statutorily designate a relator their agent for purposes of pursuing their own interest in a case.

The Court then explains why that's not enough by pointing to the fact that the statute provides that a person may bring a civil action, both for the person and for the United States Government. So there's a sense in which the individual is being given some sort of interest in the case; and then goes on to talk about why -- what aspects of the statute support that, and then says:

> "For the portion of the recovery retained by the relator, therefore, some explanation of standing other than agency for the Government must be identified."

So then this sets up the analysis that ultimately results in the Court concluding that, for the portion of the recovery that is the relator's bounty, the right way to think about standing is that it is a partial assignment of the

Government's right to recovery. And so that gives the relator an interest, even though the injury, in fact, is still with the Government, over the bounty. But it doesn't change the fact that the Court has carved out, at the outset, for the rest of it, the basis for standing as agency. So the relator is the agent of the Government.

And then the Court goes through its analysis, including, because it's Justice Scalia, not just that analytic analysis under the law, but also a detailed historical analysis of the history of *qui tam* suits, and ultimately concludes that, when combined with the theoretical justification that we just discussed, that -- finds that the standing is based on agency and this partial assignment of right, with the historical discussion that leaves no doubt that a relator, under the SAC, has Article 3 standing.

And so this case -- again, and I think it's just the Court confirming what's in the plain language of the statute, so I don't think this is anything that's overly dramatic. Whether the relator is an agent hasn't been something that's really been, you know, super important since then; it's just there. There's been more focus on the partial assignment of right part, which covers the bounty, but there it is.

So, again, we believe that, when you've got a Supreme Court, in the context of making a decision about the

standing of the relator to bring the cases, you know, it has a thoughtful analysis; points out that, under the statute, this is a statutory grant of agency, which covers some, but not the entirety of the relator's -- of the case; and then goes through an analysis for the portion of the case that's covered by the relator's bounty, and finds the partial assignment of right rationale, that it is beyond clear that, for purposes of the public disclosure bar, in a non-intervened case, where we're relying on the relator as a party -- and I'll get to that in a moment -- or really, in any case, the relator is -- qualifies, and these complaints qualify as being disclosures in federal or civil hearings, to which the Government or its agent is a party.

The next work that I wanted to talk about, or the next piece to this that I want to talk about is: Is the Government a party to the two complaints to which it intervened? There, the relator argued that, because the Government characterized in its -- so those are two cases where the Government, it's undisputed, did intervene to settle the case, and so they joined the case. The Government, in joining the case, styled its intervention in its own filing. And this is, you know, not something that the Court -- that was litigated, the propriety of which, but they styled -- chose to style their filing as an intervention, in part, and a declination, in part, signaling

that they -- because what the Government is doing here is settling and releasing, with prejudice, certain claims.

But the Government takes the position that, if it is not, itself, settling other claims that have been brought in the complaint, the dismissal of that case should be with prejudice as to the relator, but without prejudice as to somebody else, in the future, potentially bringing those claims on the part of the Government.

It is not an issue at stake in this case, but occasionally, there are disputes about whether the Government can do that, and if so -- you know, to the extent it would violate normal *res judicata* principles and all that. None of that matters here.

What matters here is, when the Government does that, Ms. Forney is arguing that the Government becomes a party only to certain claims in the case, but not to the others; and that, since the Government, undisputedly, did not settle allegations in the Schroeder and Onwezen complaints, that overlap with Ms. Forney's allegations, the Government did ever become a party in the sense relevant for application of the public disclosure bar to the Onwezen and Schroeder cases.

That interpretation of what is going on, I think, is foreclosed by the statute. And we have pointed the Court to a recent District of Massachusetts case that just kind of

collects the analysis.

I also think it's worth pointing out that Ms. Forney has not pointed to any case law supporting her interpretation of the statute to allow the Government to intervene in a claim only, and not be a party to the whole action. And so let me explain why I think this argument that has been made doesn't -- her argument doesn't work.

First of all, if you start with the language of the statute, in 3730(b)(2), it says that:

"The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information."

So, when it talks in the statute about the Government intervening, it doesn't say, when the Government may elect to intervene and proceed with claims; is says the action. And it repeats this formulation in 3730(b)(4), where it says:

"Before the expiration of the sixty-day period, the Government shall proceed with the action, in which case the action shall be conducted by the Government."

So the statute contemplates intervention as an act that brings the Government into the case. I think it's a separate question whether you intervene in the case, can you

settle some claims, what's the effect of that. I think the point here is the Government can't, just by titling and styling what it's doing, in a way that's not contemplated by the statute, you know, avoid the statute. And again, the Government -- I have no issue with whether the Government intervened in part or didn't intervene in part in those particular cases, other than to say that, under the statute, they became a party to the action when they did that for purposes, certainly, of the public disclosure bar.

The other sort of piece of this that I want to mention is to sort of just take a step back. This is also not something that's unusual or unique to the False Claims Act. If you think about a piece of civil litigation, sometimes a plaintiff sues six defendants and has five claims, and three of the claims are against two defendants, and three of the claims are against all of the defendants. Okay? So the defendants aren't necessarily in all of the claims, but Rule 4 still applies. Then every defendant, whether they're in some or all of the claims, gets served with the complaint, asked to respond. They are a full party to the action, even if they are only a party to certain individual claims. So these are not mutually exclusive concepts, for purposes of how the civil rules characterize the parties.

To the extent there's a conflict between the civil

rules and the False Claims Act, of course, the statute that provides for specific procedures would control, but there is no conflict here. So the Government, when it intervened, notwithstanding the way it styled its intervention, became a party to those actions. And therefore, those are also both actions where, not only is the relator an agent of the Government, but the Government is a party to the action. And as we've discussed, Moore didn't change anything there.

So, then the last question that I think was raised about whether these complaints meet the statutory definition for potentially being a public disclosure is whether a complaint that's not intervened and that comes out from under seal, and is subsequently dismissed, is properly considered a complaint in a civil hearing. And so, on this argument -- and I don't think, you know, even Ms. Burke pushes it particularly hard in her brief, and appropriately so. You know, she acknowledges the Third Circuit precedent, addressing the scope of what constitutes a hearing. It's a very deliberately broad definition, and has been held to include anything on a public litigation docket, without reservation.

It is certainly true that the specific context of whether an unsealed, non-intervened *qui tam* complaint that is dismissed, that specific factual context is not encompassed by these cases. But I think the mere fact that we're looking

at three cases from the 1990s shows you how subtle the law is on this. It's just never something that's had to be litigated.

And in fact, these cases are holding things like discovery in a civil hearing, in a civil litigation that's not subject to a protective order, so this isn't even something on a public docket, is still a public disclosure because it's something that's not barred from discovery from the Court, and so it's something that's potentially accessible. So the concept of what constitutes a disclosure within a hearing is very broad.

The view is very much -- and this is the rationale, one of the analogies, either in Stinson or in one of the other two cases that the Court points to, in saying, look, you know, even though arguments were made that this should be more limited to a full evidentiary hearing or something more cramped than just being on a -- being open and public on a public docket, the Court says, you know, it just doesn't make any sense to limit it that way, there's nothing in the legislative history or concept of the statute to support that after all. If you can go to a public library and pull up some random news article, and that can count as a public disclosure, but we're now going to hold that you can't go to a court and pull up a complaint on a public docket, and say that, somehow, that is barred from serving as a public

disclosure, it doesn't make any sense, and the statute doesn't require it.

And so the rationale behind, I think, these decisions of open and broad interpretation of what a "hearing" means here, and what the statute is trying to achieve, is they support, you know, declining to go down the road that Ms. Burke would like you to go down.

I'd also like to point out that she doesn't --

THE COURT: I'm -- let me interrupt just for a moment there. So you are suggesting that, if a complaint was filed and a motion to dismiss is filed, and a motion to dismiss is granted, that that still would qualify as a hearing for purposes of public disclosure?

MS. MAYER: Oh, yeah, absolutely. It's just -- if a complaint comes out a public docket, just the law is, in the Third Circuit, if a complaint is on a public docket, it's a disclosure. And if it's in a litigation, it's a hearing. And the reason why is, under the public disclosure bar, there's -- we're -- this isn't a *res judicata* argument or analogy. What it's saying is that, if there's information out in certain enumerated places in the public, then, if the Government declines to intervene in the case, the relator can only proceed with her action if the relator, in advance of filing her action, disclosed information to the Government that materially adds to those public disclosures, that she's

an independent -- that she acquired independent of the public disclosures.

And so it's not trying to say -- so it doesn't matter if those cases are ever served or dismissed or litigated beyond litigation that happens while it's under seal, of course. They're public filings on a public docket, and that constitutes a hearing. And that's where the Third Circuit drew the bar on what's a hearing.

THE COURT: Okay.

MS. MAYER: Okay. And I don't want to overemphasize this. But to the extent there's some sense that -- you know, and I felt Ms. Burke was sort of pushing in this direction, that -- in her brief, that, because these cases come out from under seal, and sometimes they are dismissed within a short period of time afterwards, that that's such a short period of time while they're live, and they may not be served, that that should somehow disqualify them.

I do want to point out that, under the False Claims Act, every single one of those complaints was filed quite a long time beforehand. It could be six months, it could be a year, it could be a couple of years beforehand. Those original complaints were served -- by statute, required to be served on the United States.

During the seal period, the United States is not

inactive. It's not as though Docket Entry Number 1 is the complaint, and Docket Entry Number 2 is an order unsealing it. Typically, in these cases -- and again, the docket is still sealed in your cases, sometimes they're out from under seal, and I can see it -- the Government seeks extensions, from time to time, of the seal. They will file a motion, they will file a memorandum in support of the motion, and the Court will consider this and rule. Occasionally, there are other sort of court business that takes place during this period. This is litigation, albeit *ex parte*, and of a very special kind.

But again, nothing momentous comes from that, other than just to say that, you know, the case coming out from under seal is a midstream event. And if it's dismissed shortly thereafter, that's fine. But it's not as though this was -- and it shouldn't matter anyway that this was a two-day case. This was a case that's been in the court process as a litigation matter for, sometimes, a very significant period of time. And it hasn't been completely ignored during that time by the United States, by the relevant government parties.

So, again -- and critically, this definition of a "hearing" that recognizes that, as long it's a complaint on a public docket, it qualifies as a hearing -- as a disclosure and a hearing, as long as it's federal government or agent,

this has been settled law in the Third Circuit since the -- you know, for decades. The amendment to the public disclosure bar didn't alter the language of hearing, which indicates, as a matter of statutory interpretation, that the Court -- that Congress was not interested in changing the settled meaning of that term.

And so, again, just sort of taking all of this together, there's just no reason to think that -- to interpret "hearing" in some new and novel way, and I think the Third Circuit precedent would preclude it. And furthermore, Ms. Burke hasn't provided in her brief any principled basis, other than the argument that these appear to be unimportant pieces of litigation, or litigation pieces that didn't go very far. She's really not pointing to anything that would support that being relevant or appropriate to point to, to, you know, run against otherwise controlling Third Circuit precedent.

THE COURT: So then there would still be the question of whether these were overlapping cases, correct?

MS. MAYER: Yes. And that's the --

THE COURT: And then --

MS. MAYER: -- next piece.

THE COURT: -- also, the question of whether the plaintiff has provided new and original information beyond what was --

MS. MAYER: Correct.

THE COURT: -- in those cases.

MS. MAYER: Exactly right. So what we've just done, maybe in more detail than Your Honor hoped to do this morning --

THE COURT: No, no.

MS. MAYER: -- but I think --

THE COURT: Because I --

MS. MAYER: -- it's important --

THE COURT: I believe jurisdictional rules should be bright-line rules; and yet, they oftentimes seem to get very not-so-bright-line, and this seems to be a perfect example.

MS. MAYER: I think so. And do want to, for a point of clarification, clear up one thing. It is -- the pre-PPACA bar was clearly jurisdictional; the language was in the statute. There is debate among the Circuit Courts right now about whether the post-PPACA bar is still jurisdictional There are some circuits that have sort of weighed in and found that it is not, and the Third is one of those in Moore.

So, for the post-PPACA piece that is left, it is not a -- it has been held not to be a jurisdictional bar. It is a basis for dismissal of the case. It is still a statutory prerequisite to suit that --

THE COURT: Right.

MS. MAYER: -- that you -- if there is public disclosure, that you are barred, unless you can show you're an original source. But I don't want the Court to, you know, miss -- to --

THE COURT: Now how does Article III standing fit in with that?

MS. MAYER: I think they are separate questions. I think the Article III standard issue has been resolved by Stevens, to say that relators, as a general class, can pursue these claims under Article III. I thin the operation of the public disclosure bar, from a jurisdictional perspective, the old on, was that the statute said a Court shall not have jurisdiction. So it's a statutory denial of jurisdiction, so it's based on a statute.

And likewise, it's now a statutory, not jurisdictional, but still a bar to suit if there is a qualifying public disclosure that raises substantially the same allegations. If you're not an original source, which is the exception that's been recognized, that's at issue here today, the case is barred, you cannot proceed, it must be dismissed.

THE COURT: Okay.

MS. MAYER: Okay. So -- but I -- but -- so it's -- so -- there we go on that. So, in terms of turning to the question of whether a relator's allegations are substantially

the same, unless Your Honor has any additional questions about that first piece, about the statutory category.

THE COURT: No.

MS. MAYER: Okay.

THE COURT: Thanks.

MS. MAYER: In terms of whether a relator's allegations are substantially the same as the prior public disclosures, we're going to address it under two theories, and we'll talk about the law.

The first thing that I do want to say here is we came forward with really specific evidence in our brief. So, first of all, the relevant comparison is you look at the public disclosures as a whole, all of them. It doesn't go with sort of a -- they don't each have to quality -- each of them doesn't have to raise substantially the same allegations, just in total, they turn into a bucket of facts and theories and fraud allegations.

So, looking at that whole bucket collectively, you then compare it against the theories that are alleged in her complaint. So, at this level, this piece of the analysis, you're comparing public disclosure to the complaint, so not depositions, not documents provided to the Government or anything like that, you're just looking at the complaint.

We, in our opening brief, went through, in some detail, where we see the -- I'm going to start with the

device check theory, the device check theory completely alleged, collectively, through these complaints that we pointed to. And so, from a factual summary judgment matter, we have kind of made our factual -- assuming, for the moment, for argument, and I hope conclusively, that the Court agrees that these complaints qualify as public disclosures under the statute, the type of document that can be a public disclosure.

And you turn to the substantial similarity analysis. We laid out, in detail, how the complaints allege the device check theory. And the key there is it doesn't have to match every single detail that's alleged. For example, you know, in her complaint, Ms. Forney alleged certain patients in the eastern -- in Eastern Pennsylvania received free device checks from Medtronic representatives as a kickback to their doctor, and that their doctor submitted Medicare claims as a result.

Those specific patients, and Pennsylvania generally, in terms of specific examples, is not in the public disclosures. It doesn't matter. What matters is the theory has been completely alleged, so that the Government is on notice that there are whistle-blowers out there in this case. There's publicly disclosed information that has all of the relevant -- sort of substantially the same relevant allegations of fraud.

Medtronic, as a business matter, is providing free device checks, routinely, across the country, to its customers. It's doing this, in order to induce them to purchase Medtronic devices. This violates the anti-kickback statute; the actual fraud is alleged. You know, here are examples of where that is happening. Under the law, under Moore and Winkelman, we've cited cases for Your Honor to look at. If you look at what -- the analysis of what constitutes "substantial similarity," that's enough.

In the opposition brief, this was where relator, if she thought there was particular allegations in her complaint that were -- that characterized her theory, and that weren't previewed by -- and weren't substantially the same as what had been publicly disclosed, this was sort of her chance to point us to those things. And she says, in sort of passing, she believes that there are meaningful differences, but she doesn't point to anything. And so we take -- you know, given that it was -- you know, having made our showing, and we believe it was her burden now to specific -- point to specific evidence that would dispute it, we don't believe she did that, and so we believe that is largely conceded. She may disagree.

But I do want to emphasize for the Court that her opposition brief was where, if this issue needed to be joined, and if she believed that there were specific elements

of her device check theory that were materially different from the public disclosures that we have asserted, she needed to put that in her opposition brief, and she didn't do it.

What she did do is that she argued that, in particular, the Stokes complaint -- which we've pointed to, and I've talked a little bit about -- should not be considered as a public disclosure relating to the device check theory because the legal theory in Stokes was different than the legal theory she's pursuing in her complaint. And my response to that is really that I think it's just getting the law wrong.

And again, we go back to the law and the statute and as it's articulated in Moore. The public disclosure bar doesn't require that the public disclosure allege the same legal theory, in order for the disclosure -- to bar it. If that were the case, then things like reports and news media would never qualify as a public disclosure, frankly, because they often don't assert a legal theory. What they do is they allege facts.

So, for example, you can have a bunch of facts showing that -- Moore is a great example of this -- showing that fishing vessels are not owned by Americans. And then you can have a different set of facts, and a different public disclosure, or even in the same public disclosure, that says, fishing vessels -- those same fishing vessels certify that

they were owned by Americans in a different place.

If you put the two together, those two public disclosures together, what Moore says, what the statute says, what everything says, is that those two transactions, X plus Y, if they show a true state of affairs and a false state of affairs, you can put them together and infer fraud from them, and that that's sufficient, right? So you don't need to actually -- for something to qualify as a public disclosure, it doesn't have to, itself, articulate a legal theory that is the same legal theory that's articulated in the relator's complaint because, otherwise, again, there would be no public disclosures, based on a lot of news media sources and things like that.

So, what Stokes does is, as I started to preview, Stokes is a complaint where the relator's theory of liability was that Medtronic was using its field sales representatives, who were programming devices and doing checks, to program these devices to expire early, so that the device -- the patient would have to come back in sooner than they otherwise would, in order to get a surgery, so they'd need more devices and generate more revenue, which is horrible.

The -- but the key is, essential to this theory -- which is not a legal theory Ms. Forney is pursuing. What is essential to this theory is that the Medtronic field people were out there, interacting with the patients, doing the

checks, doing the programming because, if the doctors were doing it, there would be no theory, right? It's only if Medtronic is doing the device checks and doing the programming after implantation and the followup that you even have the ability to implement this theory.

THE COURT: Well, wouldn't there be a theory against the doctors? If the doctors were doing the exact same thing that Medtronic was alleged to have been doing, wouldn't that have been generating false claims against the United States? Like I don't -- but trying to --

MS. MAYER: It might have.

THE COURT: Trying to tie Stokes with the facts of this case --

MS. MAYER: Uh-huh.

THE COURT: -- is a little harder, when you try to distinguish it between facts and legal theory. Obviously, the legal theory here is not at all the same.

MS. MAYER: Correct.

THE COURT: And -- but it happens to have, as facts in it, the only way they're able to do this is because they're giving these post-implant services.

MS. MAYER: Well, I think -- so, as a hypothetical, you can certainly have a case where you plead -- your defendants are doctors, and you plead that you work for a manufacturer, and you have seen the doctors reprogramming

these devices to cause earlier explants because, somehow that, you know, enriches them and causes false claims. That's not the case that Stokes pled, though.

Here, what Stokes pled -- and I mean, I'll point you to a few specific paragraphs, so we can go over them -- pled that it was Medtronic and other device manufacturers, who manufactured these types of devices, who were using their people to do this and to effectuate the scheme, and that it was done to enrich the manufacturers, who would directly benefit by having these explants happen sooner because it --

THE COURT: And it would provide these services for free, arguably for the doctors.

MS. MAYER: Yes. And so, for example, we have -- sorry, I've just got to find the Stokes complaint.

THE COURT: Because I'm a little curious. What if you took Stokes out of your bucket, and you just had Burns and Onwezen and Schroeder, et cetera? If you didn't have Stokes in your bucket, do you still have a public disclosure?

MS. MAYER: Yeah, we do. I mean, it adds to it. I think it adds relevant detail because Stokes has all those wonderful allegations, based on the MedPAR data, about the different regions, where hospitals were performing a really high level of explants. And what that gives you a further example of is regions and hospitals where you've got reps operating to do all these free device checks and

reprogrammings, to effectuate that scheme. I mean, so it just adds more color and detail to what's going on, and puts the Government on notice of it. But no, we don't think that we need it. We don't think that, without it, we lack fully qualifying public disclosure that alleges substantially the same allegations, and that material information that she, you know, theoretically or potentially, might add would qualify her as an original source.

But I think it's important that these allegations in Stokes, even if they're not the focus of the case, they are facts that do corroborate, and that do provide additional detail. I think, in and of themselves, they're not as clearly identical to or substantially the same as her theory as the stuff in Onwezen and Burns, in particular, for example; or, on the consulting theory, Schroeder.

THE COURT: Well, this -- the Stokes theory is -- I would think even the plaintiff would concede, is a much more powerful theory of Government fraud, the idea that you would deliberately try to make a device not last as long as it should last, just so you have to create more devices and generate more money for the manufacturer, paid for by the Government. That's a powerful argument, certainly more so than the argument that you are providing these free services, and that's a kickback, and therefore, it's a violation of the anti-kickback statute; and, thus, the -- what's being

submitted to the Government, where you certify you're not violating the anti-kickback statute, is not accurate.

MS. MAYER: And just for the record, the case was not intervened, and it was dismissed. It didn't -- there was no settlement where Medtronic admitted any -- I mean, it was not substantiated. This is a complaint, of course --

THE COURT: Right.

MS. MAYER: -- disclosing allegations, and not a finding, so -- but the allegations of the fraud. We believe the facts in here line up with and do -- and can be added to the bucket of the collective disclosure, for purposes of evaluating what the public disclosure was in this case, and whether it's substantially the same.

The other complaint that -- and again, just to sort of focus the Court for a second on what I mean by -- well, I think we've covered Stokes. So, when it comes to -- the second complaint that the relator takes issue with is the Schroeder complaint. And -- and again, so just to wrap up the device check theory.

So we really have -- I mean, you know, Burns' entire complaint is that free device checks were performed in order to enrich doctors; that reps, you know, got doctors -- the doctors were billing for services Medtronic performed, that this is a kickback, here's a list of doctors who did it, here's claim -- here's superbills and claim forms for it.

Like it -- this is the case -- this is the device check theory in another case that was completely publicly disclosed.

THE COURT: Is the theory that the doctors -- I understood the theory originally to be that the doctors were getting kickbacks --

MS. MAYER: Uh-huh.

THE COURT: -- that, instead of using their own people, Medtronic provided free people --

MS. MAYER: Yep.

THE COURT: -- for these device checks. But I didn't believe the theory was that the doctors then submitted a bill for that to the Government.

MS. MAYER: That's correct. The submission of the bill to the Government piece of it --

THE COURT: Had the --

MS. MAYER: -- was not --

THE COURT: -- anti-kickback --

MS. MAYER: -- is not in --

THE COURT: -- provision --

MS. MAYER: -- Forney's complaint, yeah.

THE COURT: Right. So I was never under the impression that this complaint had anything to do with doctors then -- okay. Suppose a device check is -- costs $100, Medtronic does it for free. The doctor puts it into

his bill and sends it up to Medicare.

MS. MAYER: Right. Yeah.

THE COURT: I don't think that's this theory, right? The theory is just that, in submitting the bill, you have to certify you're not violating the anti-kickback provision or statute. You -- this is a kickback -- which, obviously, you disagree with -- and therefore, you are -- that certification is untrue, so it's a false claim to the United States.

MS. MAYER: I a hundred percent agree that the theory pled in Ms. Forney's complaint and the theory -- her theory had nothing to do with doctors billing for services Medtronic provided. That was not alleged. Her theory was -- the first peak switches [sic] -- that, simply by providing the service, you're replacing someone at the medical practice, and therefore, saving the doctor that money, and that's a kickback. And then, if claims result from that, those claims are false under the 2010 amended version of the anti-kickback statute --

THE COURT: Right.

MS. MAYER: -- which (indiscernible) in that way in the False Claims Act.

THE COURT: And so, if they're not a kickback, as a matter of law, or factually, if they're not a kickback, the whole case goes away.

MS. MAYER: Yes. Yeah. The -- yes.

THE COURT: As we went over with the motion to dismiss.

MS. MAYER: As we went over with the motion to dismiss.

In terms of, you know, the device check theory -- and then you've got Onwezen, the Onwezen complaint, which alleges that, you know, device checks were done day in and day out, at high volume; that they were done for free; that they were done to induce people to use Medtronic devices. The entire theory, we've gone through it, and I can go through it more detail, if it would be helpful for the Court. But we lay out the relevant paragraphs in our statement of facts and our brief in some detail here.

And again, Ms. Burke hasn't challenged that she has anything in her complaint that is not substantially similar on the device check point to have identified any of these public disclosures, other than taking issue with the Stokes complaint for the device check theory that we discussed.

THE COURT: What the plaintiff does do is focuses on this idea that her client did not know any of this, and she's an original source of, arguably, new information.

MS. MAYER: Right. So the original source is the next piece, but first, we need to get through the substantially similar. So all I want to say is, for --

there's sort of a -- in order to say that the public disclosure bar apples to your case, you have to have a type of disclosure that fits within the definition of the statute, and what is disclosed needs to be substantially similar to what has been alleged in the complaint, and that's an assessment that has to happen under the statute. And if it does, the public disclosure bar bars the suit, full stop. The next step is, if the relator believes she's an original source, that's an exception that's recognized under the statute, and she can come forward and argue she's an original source, which, of course, she's doing that. And we absolutely need to address it.

And there is a piece -- so the original source -- there's a couple of prongs to the original source exception, one of which, you know, the relator is not asserting applies here, and we agree. The one she's going under, if -- and it does sound similar to the substantial similarity analysis, but it's not the same. But it also a comparison -- a comparative analysis, and that is one which we're going to get to. But that's the issue of whether she is an independent source of information that materially adds to the public disclosure, that collective disclosure, that she provided to the Government, in advance of filing the action. So it's information provided to the Government, in advance of filing the action, that materially adds to the public

disclosure, and she's an independent source of it.

And on the independent point, Ms. Forney, as I -- I mean, so, actually, I don't want to confuse things right now. We'll get -- I want to -- and I think we're almost done with the substantial similarity.

THE COURT: Sure.

MS. MAYER: But I want to just sort of close out that piece of it because that's really the piece where, you know, we need to come forward with the public disclosures and, you know, show that they are substantially similar to those allegations in her complaint. And then, once we finish that, again, from our perspective, we can stop. We, of course, expect, and we know she has argued that, A, that doesn't work, but to the extent it works, she wants to put herself forward as an original source. And so we're going to talk through our views of why she doesn't qualify as an original source, should -- as well.

So, in terms of the substantial similarity, we've covered the device checks. And again, I don't think it's really contested that the public disclosure, other than, you know, what we've discussed about Stokes, where I really do think there is nothing in the law that says that the facts in Stokes that do overlap with her case can get thrown in the pot for public disclosure. Although, obviously, there are facts in Stokes and legal theory that do not overlap, and

then those don't come in. And so, again, I think it would improper to exclude the parts of Stokes that do overlap, but --

THE COURT: But you're satisfied --

MS. MAYER: And we talk --

THE COURT: -- in this collective bucket --

MS. MAYER: Uh-huh.

THE COURT: -- there is the Government being put on notice that Medtronic is providing free services, with respect to these implants, that, if they weren't providing, the doctors would have to provide on their own, and thus, they are providing a financial benefit to the doctors? That would qualify as a kickback?

MS. MAYER: What -- but what I -- what we're talking about is not what -- whether the theory -- and it doesn't matter, actually, whether the theory is a legally viable theory for this inquiry. You know, in Moore, for example, the Third Circuit goes to great pains to say, we're not ruling on the 12(b)(6) issue because the defendant had got the case dismissed on public disclosure bar grounds. In that case, it was litigated at the motion to dismiss stage and had a separate 12(b)(6) argument that the relator's theory didn't pass muster as a legal matter.

The analysis of whether the public disclosure applies doesn't evaluate the validity of a legal theory. It

just says, was it disclosed --

THE COURT: But --

MS. MAYER: -- and is that disclosure --

THE COURT: But was --

MS. MAYER: -- substantially similar.

THE COURT: Was the legal theory disclosed to the Government, or just the facts disclosed to the Government?

MS. MAYER: Inn Stokes, it was facts. In the rest of the complaints, it was the theory --

THE COURT: The legal theory.

MS. MAYER: -- and the facts.

THE COURT: So you --

MS. MAYER: It was the whole --

THE COURT: -- believe that --

MS. MAYER: -- kit and caboodle.

THE COURT: -- legal theory; that is, the same legal theory being brought by the plaintiff here, was in those -- in that bucket?

MS. MAYER: Yeah.

THE COURT: Okay.

MS. MAYER: Absolutely. The ...

(Pause in proceedings)

MS. MAYER: You know, for example, we've got -- I mean, we've got -- I would point the Court to Pages 7 through the top of 9 of our opening brief for arguments that the

device check theory allegations are substantially the same as the prior public disclosures.

(Court and court personnel confer)

THE COURT: Counsel, do you mind if they bring new chairs in while we're doing this argument? If they make too much noise, we'll take a short recess. But apparently, if we don't let them bring them in, we're going to lose them.

MS. MAYER: It's fine with me. It's up to Susan.

MS. BURKE: It's fine with me, Your Honor.

THE COURT: And you'll get to see the new chairs, which should match the newly upholstered jury chairs, which we used --

MS. MAYER: Right.

THE COURT: -- for the first time over the past week.

MS. MAYER: Right.

THE COURT: Excuse that interruption, Counselor.

MS. MAYER: Sure.

THE COURT: You may proceed.

MS. MAYER: So I'll point you to those parts of the opening brief, and then we address it again in our statement of facts and our reply, I think we go through it in detail.

I think the key is that the -- these folks, they alleged devices are provided for free. That is remuneration under the anti-kickback statute, full stop. That's the key

theory here, and that's been previewed in the complaints.

THE COURT: Well, the one thing I -- all right. I look in the newspaper, and I see that Medtronic is doing something they shouldn't be doing. So I go out and I file a False Claims Act claim against them because I want to make money off of what I just discovered in the newspaper. That would barred by the public disclosure bar, correct?

MS. MAYER: So the Government could take that information and proceed on its own. But if you -- if your only source of that information was the public disclosure, yes, you would be barred.

THE COURT: Because, otherwise, anybody reading the newspaper who learns about this can file suit.

MS. MAYER: Yes.

THE COURT: And you're really not providing the Government with anything that's not available publicly because it was in the newspaper.

MS. MAYER: Yes.

THE COURT: Now, with complaints, we have it a little different. If you're talking about someone who's filed a complaint in Federal Court that alleges something, that is public, in theory, and once it's unsealed, it's public. The information has been provided to the Government. So, once one person has filed on a particular legal theory and a particular set of facts, nobody else -- the public

disclosure bar would bar anybody else from filing, unless they were an original source, adding additional facts or additional information to the Government?

MS. MAYER: Yeah, because the Government -- I mean, the purpose of the False Claims Act is to get -- is to motivate people to get information about fraud to the Government promptly.

THE COURT: Right.

MS. MAYER: And so that person, the person who's first in the door with the theory and the complaint, gets to the Government. The Government has --

THE COURT: Right.

MS. MAYER: -- that sort of first crack at it.

THE COURT: So, if ten people file, on ten separate days, it's the first in the door.

MS. MAYER: Well, and there's a separate jurisdictional bar called the "first-to-file rule," as well, which can come into play. But what I want to emphasize, though, is, if ten people file the same theory on ten successive days --

THE COURT: Right.

MS. MAYER: -- the second through tenth will not have a -- they may have a -- they'll have a first-to-file issue, maybe, but they won't have a public disclosure bar issue if the statute operates the way it normally does --

THE COURT: Because it --

MS. MAYER: -- because that --

THE COURT: -- would have --

MS. MAYER: -- first complaint --

THE COURT: -- been unsealed.

MS. MAYER: -- is still under seal --

THE COURT: Right.

MS. MAYER: -- when the second and the third and the fourth and the fifth are filed. The public disclosure bar comes into play when that first complaint comes out from under seal and is now a public disclosure, right? And the relator -- if the relator then -- even if the relator didn't see that complaint, but if another person wants to come forward with the same theory and present it to the Government, what the statute says -- and this is the balance Congress has chosen to strike -- is to say, if your information is independent of that disclosure, so you didn't just read that complaint and then rush to the courthouse, you can proceed, but only if you're bringing something more to the Government that is independent of and materially adds to the public disclosure. Okay?

So the idea is they want to create some ability for the Government not to have to look at the same theory over and over and over and over again, and for defendants to have to just defend the same conduct over and over and over again,

and to put a limit on how many times you can kind of bring a second and successive theory.

THE COURT: And so, if the Government decides not to intervene in the subsequent case --

MS. MAYER: Uh-huh.

THE COURT: -- in our case, and your argument is that the other case is the bucket, et cetera, the Government decides not to intervene, Medtronic claims public disclosure bar, who is to decide whether the relator has brought new and additional information to the Government, if the Government is not taking a position on that?

MS. MAYER: Well, you will.

THE COURT: I know.

MS. MAYER: So the law --

THE COURT: It was a --

MS. MAYER: There is --

THE COURT: -- rhetorical question. But how do I now that the Government hasn't gotten additional information from this relator?

MS. MAYER: So the key is, the question is, and the statute is set up to allow -- the enable the Court to do it. I think -- well, so the way the provision -- the original source provision works is it's the relevant comparison, under the post-PPACA bar, is that you compare the information that the relator brought to the Government in advance of filing

suit, and you compare it to the body of public disclosures. And so you're not comparing it to what the Government has in its head; you're comparing it to the body of public disclosures. Does that make sense?

THE COURT: Yes.

MS. MAYER: Okay.

THE COURT: It does.

MS. MAYER: So it's something that's actually achievable, as opposed to requiring psychic powers --

THE COURT: Right.

MS. MAYER: -- that none of us have.

I think -- but -- and there, it's -- and there is some guidance. But I think it is important to note that, when you are making that evaluation -- well, okay. So let's just wrap up substantially the same because this is a little bit of a technical doctrine, and I want to make sure we keep the buckets in the right place.

We've talked about device checks. With respect to the consulting theory, we pointed to allegations in the various public disclosures, in detail, in our case, including in the Schroeder case, that disclose substantially the same theory that relator is pressing here. And relator is -- again, doesn't really dispute that, except to argue that the Schroeder case is only litigating two theories, not, again, the theory of liability that she's asserting under these

consulting agreements. So, again, she's making that same argument that the legal theory has to match, and it doesn't. There is no legal support for the proposition that the legal theory has to match.

In Schroeder, Schroeder actually alleges a category of kickback which is providing practice management and consulting reimbursement advice as a category of kickback, and has allegations about it in the complaint; and then, in the counts of the complaint, alleges that, and incorporating by reference all the prior pleadings, there are violations of the Anti-Kickback Act. So we actually think Schroeder does plead the theory, too, and that we think that the relator simply misstates -- misstated the complaint in her opposition brief, when she characterized it as only asserting an off-label promotion theory and a theory of kickbacks related to cash for clinical trials and other things.

THE COURT: So, if there are issues of material fact as to what she provided to the Government that would preclude summary judgment, does that mean this is a defense that you raise with the jury?

MS. MAYER: So I don't think there -- well, I think -- so, in this case, there are no disputes of material fact about what she provided to -- or let me take a step back.

I think there is a record here where this issue is fully resolvable by the Court, without it going to a jury, in

this case.

THE COURT: So you don't believe there are any contested facts. It's just whether the facts fall within the public disclosure bar.

MS. MAYER: The -- so, turning to that because you're asking a specific question, I do think turning to the question of an original source, I think the first thing you have to look at is -- so assume we've gotten through substantial similarity, and so we've shown qualifying public disclosures, raising substantially similar -- and they really -- they don 't have to be the same, they just have to be substantially similar, under the law -- the theories, as to what she's pursuing here, collectively taken as a bucket.

Then you move to the relator is arguing she is an original source. And she's going to qualify it by saying she's -- her information, that she provided to the Government in advance of filing of the case, is something that she was an independent source of, it didn't come from her looking at those complaints. She has a statement in her declaration that she never saw the complaints before she saw our summary judgment. We're not contesting that. So she's independent, whatever the information she provided to the Government is independent. I want to be clear on that.

What we're talking about now is what -- the first question is: What information did she provide to the

Government in advance of filing -- in advance of filing the action and commencing the action? That's what the statute says we need to look at. And so the first step here is: Well, what is that?

And I think it's a good place to start, and it's an important place to start because there is only one category of information that is -- has even been proffered by relator that meets that definition, and that is the stack of documents that she gave to the Court and identified for us, for the first time, in her opposition brief ten days ago. So that is the information that she contends she provided to the Government in advance of the disclosure.

And I say "contends," and I mean -- I don't want to pick an unnecessary fight. But I think it is important that we start with also noting that her evidence that this set of documents was provided to the Government in advance of filing suit is based entirely on declaration by Ms. Forney that her lawyer told her that this is the set of documents, and the lawyer told her that these documents were provided to the Government in June of 2015, which would be in advance of filing the action; and that, under the rules of evidence, which do apply in this proceeding here, that is hearsay and inadmissible.

There is no exception that my lawyer -- communication from a lawyer as a hearsay exception. There is

a catchall hearsay permission that a Court can invoke, if they believe the information is reliable enough to do it. But that's something that should be rarely invoked, and it's certainly not something that should be routinely invoked for statements from counsel to client.

I also want to -- and so I believe, as a first step, that the Court -- that there is no admissible evidence of a disclosure of information to the Government, in advance of filing suit, because the only evidence that such a disclosure was made is based on hearsay declaration by -- hearsay statements in the declaration by the relator.

We, obviously, tried to deal a little bit with the merits of the documents in our brief, and we're, obviously, prepared to address it. But I would be remiss if I didn't point to it. We did object to those statements in her declaration in our responsive statement of facts, preserving this evidentiary issue.

The second thing I wanted to point to is that, when we're talking about the documents and what they are whether they're here, I think -- and as we proceed into this part of the hearing because -- you know, I'm open to what's going to be most useful to the Court, in terms of how to proceed. There are a couple of very unusual things about the way this is being teed up for the Court in this case, that I think all can be dealt with.

First, the relator herself does not emphasize or really take any time arguing that these documents support her case for being an original source. They are mentioned only on the last page of her brief, in a single sentence, where she says, in conclusory fashion, that these documents contain information that materially add to the public disclosures.

She points to the statement of facts in support of that, but the statement of fact provisions that she points to aren't statements of fact that identify anything in those documents that she believes materially adds to the public disclosures. They're pointing to the pieces of her statement of facts that go through the history of Medtronic's repeated efforts to get her to disclose her communication to the Government, and what documents she provided and her -- you know, just sort of the history of how the record on that evolved, which we can talk about in just a moment.

The second thing that I want to point to, so, in her opposition brief, where she had every opportunity to -- I mean, even put aside the hearsay issue with this evidence. She had every opportunity -- these are her documents -- to go through and point the Court to where in these documents there are new, material details, that she believes materially add to the public disclosures. And we believe it was her obligation to do that, under the Court's standing order, under the local -- under civil rules. This is what you do.

You don't just sort of give 900 pages to the Court and to the defendant and say, as a general matter, I think there is information in here that materially adds to your public disclosures, you should have put me on notice of your arguments in advance, which is what she says in her brief. So I don't, essentially, have to do anything in response.

I think that, you know, independently, just in terms of just failing to highlight for us, it -- you know, it's going to be challenging, although we're -- we'll do it, if it will be helpful to the Court, to go through these documents and respond on the fly, in a meaningful and effective way, to why we believe whatever she might point to -- and I don't know what that is -- is something that's materially new and different.

There are a couple of other issues here, and I just -- I don't want to belabor it, but I do want to mention because it's in our statement of facts, the history here. We did ask, in our request for production of documents, for communications with the Government, that the relator had with the Government. We were told no. Ms. Burke has said -- and I believe her -- that she produced to us, in her productions to us, the actual documents that were produced to the Government. And we certainly have had the documents and others that have the Bates numbers in the set that was provided to the Court.

What was never provided to us was the non-privileged portion of any communication to the Government. And by "non-privileged portion," what I mean is, if I ask, in a request for production of documents, for your communications with the Government, and you believe, for example, that you transmitted documents with a cover letter, and that the content of the cover letter is privileged, what I believe the appropriate thing to do is -- because they're not contending the documents are privileged -- is to produce that communication, minus -- as a set, these are the documents -- with an indication that a privileged letter was withheld, based on privileged, and then, you know, a privilege log that says, here's the date of that communication; or you redact the letter, if only portions of it are privileged, and you produce it. The key is I was entitled to get that, what was communicated to the Government, that set of documents, as a set of documents, identified as communications with the Government, because I asked for it. I was told, no, we're not going to do it, you know, it's, again, privileged.

So then I asked an interrogatory, to identify communications to -- with the Government, who had them, when they occurred, and what the substance of the communications were. Again, a great opportunity to say a chunk of this is -- communications with third parties, which includes the

Government. I was looking for other third parties, as well. Lots of objections, including privilege, including there's easier ways to get the information.

For purposes of this disclosure of documents, it would have been very easy to stand on all privileges, but also say, documents with the following Bates numbers were produced to the Government, you know, on September or June or July or August X, whatever. We didn't get that information.

We deposed Ms. Forney, and her deposition is attached here, and the relator's counsel cites the relevant portions of the depositions. And I asked her, you know, when were disclosures made to the Government. And she initially said a date in 2016, and then corrected herself and said, you know, I believe it was June of 2015. Why do you believe it was June of 2015; I recall my counsel telling me, at that time, that she was disclosing documents to the Government." So that's the date. And that statement, in sum, is what Ms. Forney is relying on now, to establish the date that the disclosure was made, my counsel told me, I recall, in June, that it happened.

In terms of what was disclosed, I asked Ms. Forney what documents were disclosed to the Government. I showed her a couple individual documents. I mean, the -- Your Honor can see, I mean, you have a stack of 875 pages. By my count, it's about 50 discrete documents, and it's not the complete

set of what was produced to us by Ms. Forney. There are others.

You know, I asked her about a couple of discrete documents, and she was able to say, yes, I believe this was produced to the Government. But there was another document I showed her, and she said, I don't recall, I don't know. I asked her, well, were the documents that you disclosed in the complaint what you produced to the Government; yes, there are 10 or 12 documents, that sounds right. Later, she said, you know, I've given it some thought, and I don't want to commit to 10 or 12. I'm paraphrasing her, but her quotes are in the testimony, it could have been 1, it could have been 5, I'm not familiar with how the production was formatted, I don't know whether it went as 1 document or 5 documents or 10 documents or 12 documents.

What kind of documents, you know what documents did you produce? And she gave me a list of, well, there were some HR documents and some training documents and some HIPAA violation documents, some promotional material, reimbursement consulting. And the list is -- again, it's in the relator's statement of facts, but it's a generalized description of documents.

And so we left the deposition with a witness who could not tell me the set of what was produced to the Government. To the extent she could tell me, she had

endorsed the view that it was 10 or 12 or maybe 1 or maybe 5 documents, but I don't really know what the document boundaries are, that sounds -- that all was her best effort to tell me. And she gave me a general description of kinds of documents that was very consistent with it being a set of somewhere in the range of 10 or 12 or 15 or 20 or whatever. She wasn't saying it could be 50. And so she clearly didn't have personal knowledge of the contents of the set of documents, sitting there that day, at the front of her mind and memory.

So I think what I -- as we turn to this analysis of whether relator has provided admissible evidence of a disclosure to the Government in advance of litigation that we should analyze, to evaluate whether it materially adds to the public disclosures, you know, I think it's important just to have this context in front of the Court, where we worked very hard during discovery to find out what this disclosure was, so that we could, ourselves, assess it, so we would have had the opportunity to ask her at deposition about particular documents, and if we had questions about it.

And critically, you know, put that aside, I think, for purposes of evaluating the public disclosure bar, to just know what was disclosed in advance of the litigation, and we didn't get that information until the Court got it. It was contemporaneous. We got Exhibit 17, which identified, for

the first time for us, in a declaration, these Bates numbers. It corrects her deposition testimony, to some extent. And to the extent it contradicts it, I think it would be improper. I think there's an open question whether it supplements it, versus contradicts it. And I -- you know, I don't want to get bogged down in evidence issues.

But then Ms. Burke had an opportunity in her opposition brief, given this history, to sort of move this ball forward in a meaningful way, and tell the Court and tell us, in her brief, what it is that she believes, in those documents, materially -- if anything, materially adds to the public disclosure because the complaint is irrelevant at this point. It was not part of that set of documents, and so it's not something that was provided to the Government in advance of commencing the action.

Testimony, declaration statements about what a wonderful employee Ms. Forney was, about -- the rest of her deposition, irrelevant. We are looking only at the information that they contend they disclosed to the Government in advance of the litigation. And it's, at best, that set of documents that was produced to the Court, and that's captured by the Bates ranges at Exhibit 17.

And so, when we're figuring out, you know, what to do with this, Ms. Burke had an opportunity to specify for the Court and for us, and I think the rules require her to

specify for us what that is, and she didn't do it. I'm sure she's fully prepared today to do it. But the problem is it's not just an abstract problem. We are going to have to try to go -- this is a very fact-handy, a very fact-intensive analysis, if the Court rules that this information is admissible, and it can be considered at this stage of the case, and for purposes of the summary judgment hearing.

Again, you know, I think there -- you know, some of it is easy to dispose it. You know, there are -- as we've described in our reply brief, there's a company of the AdvaMed Code. The AdvaMed Code is cited in the -- you know, is attached, actually, to the Burns.

There are, you know, statements of Medtronic corporate compliance policies that are, again, largely irrelevant, and they don't advance the ball on any fraud allegations in this case. They just show that Medtronic had a compliance program. It doesn't -- you know, to the extent that that's not previewed in the prior public disclosures, that certainly doesn't add anything that's, you know, significant and essential to the fraud in this case.

There are examples of promotional materials for consulting services that, on their face, don't say anything about providing for free. And there's no context around these documents. There are some consulting materials that do say they're provided for a fee. There are long -- there's a

number of composite documents that are printouts of what Ms. Forney has said at deposition were printouts of a Google calendar, these are the HIPAA violations she averted to; and that one of which was, ultimately, the source for the allegations about particular patient device checks in the complaint. And we've addressed that, and we can talk more about that as we need to do so.

But I think the key is, you know, we looked through these documents, and we don't see anything in them ourselves that even arguably supports the fraud, let alone materially adds to it, under the demanding, high-bar materiality standard that the Supreme Court has said applies in the False Claims Act context, and that is harmonized with the approach the Moore case took, the Third Circuit took in Moore

But I'm -- I really -- before we try to do whatever we're going to do in this regard, I really think it's critical to just set the context here, and say that, you know, we're going to be kind of, you know, doing this on the fly because we've been put on absolute -- despite trying, you know, our best efforts, we've been put on absolutely no notice of what Ms. Burke may or may not contend is material here. And I think that, in and of itself, along with the, you know, admissibility issues and all that, raise sufficient questions that the Court could certainly, in its discretion choose to disregard that stack of documents.

THE COURT: And do you think it would be appropriate to shift the argument over to --

MS. MAYER: I think so.

THE COURT: -- Attorney Burke? Why don't we take a ten-minute recess because I do want to check on these chairs, and you have been arguing for an hour and a half? So why don't we take a ten-minute recess, then we'll start up with Attorney Burke. You will explain why you believe these documents provide additional information to the Government, and that they were provided to the Government.

THE COURT OFFICER: All rise.

(Recess taken at 11:24 a.m.)

(Proceedings resume at 11:41 a.m.)

(Call to order of the Court)

THE COURT: This is still the old chairs, I think.

UNIDENTIFIED: Yes.

THE COURT: You can be seated, thank you.

MS. BURKE: Your Honor, they appear to be in the hallway outside.

THE COURT: Okay. Well, they might make some disruption, but hopefully, not too much.

The Court is called to order. All parties previously present are once again present. Attorney Burke?

MS. BURKE: Thank you, Your Honor.

Let me begin by explaining that I'm going to cover

this in two parts. The first, and most important, is whether or not the Government or its agent is a party in the lawsuits that Medtronic has proffered as the public disclosures. It's the relator's position that, neither the Government, nor its agent is a party in any of those lawsuits, and we'll walk through -- we'll walk Your Honor through that.

We will then turn to the analysis that is called for by Moore for the original source, and walk Your Honor through the fact that Your Honor's prior ruling, under Rule 9(b), actually has law of the case impact, and is the same analysis that you need to conduct here, in order to find that relator is, in fact, an original source. The level of specificity and the level of detail that were provided in the second amended complaint that survived the motion to dismiss is the same detail, the same information, and the same specificity that, under Moore, is required to clear the original source bar.

But turning first to this critical issue of first impression. Medtronic argues that we said that Moore somehow rewrote the statute to exclude the word "agent." Not at all. In their brief, they had claimed that the Government was a party. We filed a brief, pointing out that that can't possibly be true because the Supreme Court has held that the Government is not a party in declined actions.

For the first time then, in their reply brief, they

come forward with a new argument, in which they don't contest our dispositive case law, which proves that the Government is not a party, and instead, they make, for the first time in the reply brief, an argument that, well, the Government should be considered a party because the relator is its agent, and for that, they rely on a Supreme Court case that was issued in 2000.

The problem is that they are not actually relying on the holding of that case, and they are failing to disclose critical language. In that case, the question was: How does the relator have standing? One of the arguments proffered was that, well, the relator has standing as the statutorily designated agent, and the Court noted that argument. It then -- and I'll read -- and that's the portion that the -- that Medtronic read to you. The Supreme Court, however, held that that wasn't right. It states, and I quote:

> "This analysis is precluded, however, by the fact that the statute gives the relator himself an interest in the lawsuit, and not merely the right to retain a fee out of the recovery. Thus, it provides that a person may bring a civil action for a violation of Section 3729 for the person and for the United States Government."
>
> Citing 3730(b).
>
> "It gives the relator the right to continue as a

party to the action, even when the Government itself has assumed primary responsibility for prosecuting it, entitles the relator to a hearing before the Government's voluntary dismissal of the suit, and prohibits the Government from settling the suit over the relator's objection, without a judicial determination of fairness, adequacy, and reasonableness."

And I omitted all the statutory cites that they included in there.

And then it concludes, the Supreme Court concludes: "For the portion of the recovery retained by the relator, therefore, some explanation of standing, other than agency for the Government, must be identified."

The relator cannot be the Government's agent. It doesn't advance the Government's interest; it advances its own interest. The Government is not bound by what we, as the relator, do. We can't dismiss the lawsuit. We cannot even decide on the terms of settlement. We are not the United States's agent. And there is an entire body of case law after this Supreme Court decision, including the Supreme Court decision that we cited to, a 2009 decision, that very clearly holds that the Government is not a party in the lawsuits when they have declined. To accept this novel

interpretation that Medtronic is putting forward, that somehow the relator is acting as a Government agent, would turn the entire statutory scheme on its head.

It's also nonsensical to think that Congress, which is well aware of the case law finding that the relator is not an agent, but instead, is a -- and the phrase is made very clear by the Supreme Court, as they talked back to the dissent. In Footnote 4, they made it very precise:

"More precisely, we are asserting that a *qui tam* relator is, in effect, suing as a partial assignee of the United States."

That is the phrase that captures the relationship between the relator and the United States. If Congress, in dramatically, radically lowering the public disclosure bar, wanted to subsume, within its new shrunken public disclosure bar, all declined *qui tam*s, it easily could have referenced the relator. After all, the term "relator" is used in the statute to refer to the relator. By contrast, the term "agent" is used in the statute to refer to CMS and the other departments, the parts of the United States that do, in fact, as an agent; so, therefore, like a false claim made to the United States or its agent, meaning it's paying agent.

And of course, as Your Honor is aware, the definition of "agent" is a legal definition; it means one who is entitled to act for. The relator cannot and does not meet

that level.

And so what we're dealing with here is a situation in which this bucket of public disclosure that Medtronic has gathered up from reviewing Pacer files, and finding declined *qui tams*, none of which were actually litigated in any way, this bucket is a bucket that doesn't rise to the level of an eligible bucket under the statute. The -- prior to the amendment, any lawsuit counted. So, prior to the 2010 amendment, those would have been public disclosures.

But Congress decided, wait, we think too many *qui tams* are being dismissed, we think the balance that we're trying to strike of incenting people who know information to come forward has tipped too far towards the defendants. Fraud remains a tremendously, huge financial burden on the Federal Government. We're going to right that balance by enormously and "radically," as the Third Circuit has called it, by shrinking the types of things that qualify for public disclosures. And one of the main ways they shrunk it was to say only a fraction of litigation actually counts as a disclosure. And that fraction is the fraction where the United States is a party, or its agent is a party. And so we don't have that here.

And so, Your Honor, at the outset, it's important to understand this isn't a jurisdiction inquiry. And in order to make the decision as to whether we even have to get

to the original source analysis, Your Honor first has to decide that there's been eligible public disclosures. We don't think there are any.

And the -- I want to turn next to -- the argument is clear as to the ones where the United States declined in full. Those are simply crystal-clear. That then leaves two in which the United States declined, in part, and intervened, in part. And then they immediately settled it, with Medtronic paying 23.5 million in settlement for the allegations that they had paid kickbacks. So turning to that -- just that issue, which we think is the only kind of wrinkle in what is, otherwise, clear-cut, non-eligible disclosures.

Let's look at what it means when the United States intervenes, in part, and declines, in part. When we look at that, Your Honor, we say, all right, the United States is deciding that it is going to become a party to an action, as to a certain degree. Had Medtronic not settled the lawsuit, and had the United States intervened, it would have filed a new complaint as to just the conduct that it's going after. That's the way the United States handles the False Claims Act cases. They want to make sure that they control what they're intervening on, and they want to make sure they're not forced to intervene on other matters.

And so, in this instance, the United States very

clearly said, we want to be a party to this case, as respect to this covered conduct. We've investigated that, we think Medtronic is at fault, and we want to pursue Medtronic for this conduct. The other conduct, it said it was declining to intervene.

Now we -- there is no case right on point as to the meaning of that. But the case that's proffered by Medtronic to suggest that, somehow, because they intervene in part, they have to be held to intervene in full, is completely inapposite. It's a District Court decision out of Rhode Island. And there, they were talking about two different lawsuits: A Wisconsin lawsuit and a Rhode Island lawsuit.

The Rhode Island relator -- the Government had intervened, in full, in the Wisconsin lawsuit, was clearly a party and intervened in full. The Rhode Island relator was trying to say, well, you know, yes, they intervened, but they really were only interested in this subset. No, they had intervened in full. So that case doesn't give you any guidance, it doesn't shed any light on the problem.

What I can tell you is that, at least since the late '90s, when I was at DOJ in the Civil Frauds Section, the United States has always successfully managed to pull its -- define for itself when it is going to be a party. And the practice of intervening, in part, and declining, in part, has not been barred by the Courts. The Courts have permitted it,

they have gone along with it, just as it did in the Onwezen and the Schroeder matter. The Court signed off on that approach, and the Court signed off on that settlement.

And so we think, Your Honor, for that reason, given that there has been no opposition and no case law in which the United States is prohibited from intervening, in part, and declining, in part. And the case -- the very case at issue here, the Court did not prohibit it. So, therefore, we can assume the Court allowed -- that particular Court allowed the United States to become a party, to part, and not a party, to part. And there's no reason why Your Honor should look behind that court order or that ruling or that settlement.

So we think, therefore, the only relevant part of the case, the only statutorily eligible public disclosure is the case that is described by the covered conduct. And we laid that out for Your Honor, it's laid out in detail in the settlement agreement, and it has no overlap, it has no similarity with the facts and the allegations alleged in Relator Forney's complaint. So, for that reason, we really think that Medtronic has come up empty in its effort to scour pacer and try to find something that would suffice as a public disclosure. We do not think any of those complaints survive analysis under the amended version.

For that reason, Your Honor, and because, as Your

Honor -- as we had stated before, we believe the Rule 9(b) analysis controls, we -- when we talked about the rest of it, we simply pointed out what we thought were fairly straightforward and self-evident points for Your Honor.

Number one, the Stokes case has absolutely no overlap. It had -- it involves a different scheme. It has simply -- it does have one allegation, in which it states that this conduct is happening, that device interrogations are performed by the device representative themselves. But it does not give any names of physicians, names of clinical specialists, or hospitals, dates, times, places, no detail whatsoever that overlaps in any way with the free device checks that we have alleged in our complaint. There's just no overlap at all.

Similarly, there is no overlap with our practice management consulting. Our practice management consulting has been pled with care in the complaint. It is -- it comes from this terminology of lean sigma, it's a particular type of practice management consulting that was started recently; in fact, after the folks who are relators in these other matters were even with the company. So Stokes is the most clear-cut. It just -- there is no overlap; it doesn't relate in any way.

The Onwezen and the Schroeder are similarly deficient, in terms of the overlap. They go into that case.

Those are the two that were settled, right? So, even if we assume that the entirety of the complaints, you know, even if Your Honor is not persuaded, as we are, that these aren't public disclosures, and even if you were to look at the entirety of the complaint, you're still not dealing with overlap. There's no details, Rule 9(b) details, about the free device checks, no names of doctors, no locations of practices, no dates of the device checks given for free, no names of the staff providing the checks. And again, there's no allegations that relate to the lean sigma consulting whatsoever. So there's just not an overlap with the Onwezen case.

Schroeder is the same. He worked in business development, and he really -- he really had a lot of detailed information about the payment of kickbacks, including different kinds of free services, but not the ones that are at issue in our case. He -- first, on devices, he doesn't even allege that, so there's no physicians or dates or device checks dates at all.

But then, on the -- even on the practice management consulting, his main focus is on the off-label promotion, which doesn't overlap. And the payments of kickbacks that he was referring to had to do all with cash and dinner and trips and studies and the like, which, of course, the United States intervened and settled some of those because they agreed that

some of these studies and the kind of management consulting that was being given was actionable, and the 23.5 million settled all of that. But that's all conduct that's separate from our lean sigma consulting.

Relator Forney has laid out the kind of reimbursement and administrative help and practice management, and it was done through this -- you know, the terminology was "lean sigma," and that's they went into the practices and said, you know, okay, we've got this, you know, key staff, who have been trained in this lean sigma approach, and we're going to come out and give you this free advice. None of that is mentioned in the Schroeder case. So Onwezen and Schroeder, again, you have no substantial overlap.

That leaves the other two cases, the Burns case and the Doe case. And there, you do have -- you do have a similar -- you do have a similar theory of liability, and you have details. So you have Rule 9(b) specificity that's required. And so what we need to do, what we need to look at, both for the overlap issue, as well as for the original source analysis, is we read more, we read the Third Circuit's teachings.

And we say, okay, as I sit here today, how am I supposed to figure out, I've got two complaints that, were the United States had been a party, which it wasn't, would be public disclosures. But say Your Honor thinks that they are

public disclosures, okay, let me look at Burns and let me look at Doe. In both of those cases, they did have specific details that they pled, and that they pled in relation to the device check theory.

In Burns, he pled that -- in Paragraph 29, he pled that free device checks were done by Burns, by himself, for Bradenton Heart Center, Lakewood Ranch Cardiovascular, Pinnacle Cardiovascular, Advanced Cardiology, Aldrich Cardiovascular, Heart and Vascular Center. That's in Paragraph 29.

In Paragraph 30, he alleges, not that he performed the device checks, but that he observed the same conduct, so, presumably, observed other Medtronic employees doing so in Naples, Florida in 2001 to 2002, and in North Carolina in 2001 -- 2000 and 2001.

And then, in Paragraph 30, he identifies Dr. Joseph Pace as someone who billed for device checks that were done by Burns.

And in Paragraph 43, he identifies healthcare providers that didn't supervise his work as Bradenton Heart Center, Lakewood Ranch Cardiovascular Center, Healthcare America. All of those are located in Bradenton, Florida. So, when you measure what -- so that's -- those are Rule 9(b) specific details that are of the similar ilk as Relator Forney's.

To the same effect, in the Doe case, there is one allegations that is similar, and that is -- first off, just as background, the Doe Relators are not Medtronic employees. They're board-certified cardiologists. And they are making the same allegation that Relator Forney is, is that these are kickbacks, and that they were being induced to use Medtronic and the other devices by all this free service.

And in particular, Relator 2 -- they're anonymous, so we don't know who that is. But Relator 2 made rule -- allegations that read the Rule 9(b) specificity level in Paragraphs 110 to 115. And he alleges that, on September 24th, 2014, a Medtronic Senior Clinical Specialist performed a free interrogation of a pacemaker without any physician being present. At the conclusion of the device check, the Medtronic Clinical Specialist completed a billing sheet, marking the CPT Code 93280, for a global billing, rather than using the required 26 modifier. So, between that -- Doe, that paragraph, and the other paragraphs in Burns, that's -- those are the specific details that Your Honor has before it, that you need to then compare with the specific details that Relator Forney was able to bring forward.

And what are the details that Relator Forney is able to bring forward? What you need to do is -- first, what you need to do is tackle this notion that Medtronic is claiming now that, somehow, Relator Forney didn't bring any

information, didn't bring any evidence forward.

And I would point out that it was completely Medtronic's option as to when they filed this motion for summary judgment. It was a surprise to us. We were not aware -- prior to the deposition of Relator Forney, we did not even know public disclosure was a factor. We only learned of it during that deposition. Relator Forney did the best job that she could and provided answers, in which she did testify what was given to the Government. She testified that everything in the second amended complaint, all of those documents, had, in fact, been given to the Government.

She testified to the best of her recall about the specific documents shown to her. And during the colloquy with counsel, I also represented to Medtronic that the -- that we had produced all of the documents. Medtronic was not forced to file the motion without doing further discovery. If they wanted to know in advance, before this particular argument session, they had the right to hold off on filing.

In fact, as Your Honor knows, we think this is all premature because it's not a jurisdictional motion. It's just another discretionary argument that they were free to make on summary judgment at the end. So, in terms of their -- you know, their argument that they've suddenly been blindsided, quite the opposite. They, alone, controlled when this was filed, and they, alone, controlled how much

discovery they did. They could have served discovery on the Government, if they wanted to hear from the Government what documents we had given them. They didn't do that. They could have served discovery on us, saying, identify the Bates numbers of the documents that you gave to the Government. They didn't do that. So, you know, from our perspective, the notion that, somehow, we were remiss is contradicted by the record.

What we put in the record, and what Relator Forney testified to is that everything that's talked about in the SAC, all of those documents were given to the Government. Your Honor has already had to review the SAC to decide -- the second amended complaint -- to decide whether or not it had enough detail to survive their challenge. As you will recall, they challenged it as lacking specificity. They challenged it as not having enough national information to survive, and that the case should be confined. They also had not only you rule on that, but they also had the Magistrate rule on that, so that's been ruled on twice already.

And I would just refresh Your Honor's recollection of the paragraphs in the second amended complaint that provide this kind of detail that is far and above and different from the detail that Burns provided and that that cardiologist provided.

First, Paragraphs 4, 5, and 12 give Relator

Forney's background. They explain how she was with the company for a long time, and how -- where she gets her insights from.

Paragraphs 18, 20, 21, 22, 23, 24, and 25 all give specific Rule 9(b) details that go to the how and the when. They talk about the payment of commissions; the fact that all of the clinical specialists and others were incented, financially incented.

And Your Honor, just to refresh your recall, the Moore Third Circuit teaching says, okay, when I'm sitting here as a District Judge, and I'm trying to figure out whether the body of information is enough to serve as an original source, I look to see, did it give the Government new details, new specifics about the how, the what, the when, and the where. On the financial incentives, that's all brand new. It's all brand-new details of the implementation.

Relator Forney brings forward Paragraphs 26 to 28, details about the training; again, brand-new details about the implementation, none of which is in any of the other documents.

Paragraphs 29 to 32, that goes to the specific dates, the patients, the types of services, the precise details and what was done; all brand new. None of that, none of that overlaps. None of that was known by Burns, none of that was known by that cardiologist in New Jersey.

Paragraph 49, again, additional details on the what? Examples of dates, doctors, patient names. Number -- Paragraph Number 50, Paragraph 52 and 53, again, all brand-new, specific details.

This information, Your Honor has already ruled, sufficed to satisfy the challenge under 9(b). That very same information suffices to satisfy the challenge under the public disclosure bar. It is the same analysis. The Third Circuit said courts should look to Rule 9(b) as a guideline, as a guideline to how to think about what kind of information they're looking for.

And Your Honor, the second amended complaint itself refers to the documents and quotes a lot of the documents. We have provided Your Honor the universe of documents that was provided to the Government. Those documents provide a substantial amount of specific, individual detail well and above what we put in the very detailed second amended complaint.

For example, in addition to all of the examples of the free device checks that are crafted in the second amended complaint, the underlying Google calendars that Medtronic has had since the very beginning of discovery, and has been on notice of, even with the filing of the complaint. We've always made crystal-clear that the calendars are at the hub of this case because the calendars provide the detail of when

a device check was given, who it was -- who it was given to, who it was given by, and the date that it was done.

So the documents Bates-numbered 01249 to 1772, and 02252 to 2274, voluminous amounts of additional calendar, more detail. All of that detail is completely new to the Government. It was not in any of the public disclosures, it was not known to those relators.

So Relator Forney is exactly the type of relator that is bringing forward a huge quantity of specific, detailed information about the who, the what, the when, and the where, the implementation of this fraudulent scheme. The question to ask is: Does her information make the quality of the case against Medtronic better? That's the test that Moore laid out. And clearly, it does.

It's illuminating, in fact, that the other relators, who had a fairly limited window, they weren't -- they were -- one was a -- one was a clinical specialist and a sales rep himself, so he knew of his own conduct. One was a cardiologist, who had Medtronic come into his office, so he knew of that conduct. But those are very narrow windows, compared to Relator Forney's window. She supervised a team, so she had access to the entire team. Plus, because she was management, she had access to corporate-wide information. So she's clearly the type of original source that is bringing forward a substantial quantum of additional information.

I would also point out, Your Honor, that, within the documents that we gave Your Honor is substantial additional detail on the value selling, the practice management, more names of the -- more names of the clinical specialists who were involved in this fraud. You can look at those at 02275 to 276, a whole list of names involved.

You can read the value selling pamphlets, the training, where it teaches the Medtronic clinical specialists how to go out there and offer these as a form of kickbacks. That's at 1915 to 2146.

There's strategic planning documents, there's more on the financial incentives that all of these salespeople are given. There is educational packets on exactly how these folks are taught to go in and curry favor with the physicians, and to get the physicians to commit to brand loyalty. So the information that has been provided to the Government and has been provided to Your Honor is a substantial body of information that improves the quality of this fraud case against Medtronic.

It's not coincidental, Your Honor, that all of these other cases that were brought were never litigated. They were dismissed immediately. The Burns case was dismissed six days after it was unsealed. Stokes was dismissed while it was still under seal. Doe was dismissed one day after it was unsealed. And the Onwezen and

Schroeder, Onwezen was dismissed the same day. And Schroeder had no activity, and they appear to just have neglected to close the case, and a clerk just, later, closed it, absolutely no activity.

It is an open question in the law as to whether that type of activity actually suffices to qualify under the civil hearing prong. And Your Honor, this, again, is a new legal issue for you. I don't think you have to reach it because I think the better decision is that these are not public disclosures that qualify because the United States is not -- neither the United States, nor its agent.

But I would just note this, in -- as a last point for Your Honor, that, were you to consider the United States or its agent as a party, I would encourage Your Honor then to go the next step and say, okay, in these particular circumstances, does that body of case law that sits out there, that says that civil litigation counts as a hearing, does it -- can it apply in these kind of unique circumstances. We don't think so.

We don't think you need to get there because we think, first, you should rule that there is no statutorily eligible public disclosure. And that's why I left that to the end because it is a novel point, and there's not a lot of law to give Your Honor guidance. But I just raise that as yet an additional reason why we don't think that there's any

way that Medtronic is entitled to summary judgment here.

So, just to recap briefly, Your Honor, we first believe that you should deny the motion for summary judgment on the very simple and straightforward grounds that neither the United States, nor its agent is a party to any of these lawsuits. We think that that applies very directly and clearly, without even any discussion, to four of the cases -- excuse me -- to three of the cases. And we think it also applies just as clearly, but perhaps worthy of some discussion, to the Onwezen and Schroeder because there is the additional point that they did intervene, in part.

So we think that -- we think that, when you do the analysis, and you look at the conduct that's inter -- been intervened on in the Onwezen and Schroeder case, and you look at the fact that there was no intervention on Burns, Stokes, and Doe, Your Honor should reach the clear, legal conclusion that Medtronic has failed to put forward a statutorily eligible public disclosure.

We, second, think that, were you not to hold that way, you, nonetheless, should hold that these -- given the particular circumstances of all five of these civil complaints, none can be found to have been done in the context of a civil hearing, that -- you know, that, although as a general matter, litigation and documents filed in litigation are presumed to be leading to a hearing or part of

a hearing, in these cases, we know, conclusively, there was no hearing. They were all dismissed with no hearing. So, therefore, that general body of law does not apply here. Your Honor knows, from the actual facts of these cases, that there was no hearing. And so, therefore, it, again, puts these outside the statute.

The second reason that Your Honor should deny the motion for summary judgment is that Relator Forney easily, easily clears the bar of being an original source. She brought forward substantial information, which is memorialized in the second amended complaint, and is backed up by the documentation provided to Your Honor; significant Rule 9(b) details of the how, the what, the when, and the where of this fraudulent scheme. The quality of the case goes way up with her involvement.

That's exactly the reason why Congress re-balanced the public disclosure bar, and lowered it radically. That's why the Third Circuit, when it reviewed how a District Court Judge should decide these issues, gave Rule 9(b) as the guidepost and the guidelines. Your Honor has already found, through Rule 9(b), that those allegations suffice. The same ruling applies here. And for all those reasons, Your Honor, we believe that you should deny Medtronic's motion.

THE COURT: Very well.

MS. BURKE: Thank you.

THE COURT: Thank you, Counselor.

Attorney Mayer, did that give you something to respond to?

MS. MAYER: Yes. I'd like to start kind of in the reverse order of the way I did my original presentation, and respond to the arguments about original source first, although I do want to address some of the points she made about the interpretation of whether these complaints fall within the scope of what the statute allows to serve as a public disclosure, as well, because I think she's missing Stevens. And I'd like to point out to the Court my views on that, as well as a couple of other things.

But let's start with the back end for right now, and let's start with what she's doing with the -- sort of trying to combine this analysis of whether the allegations in the public disclosure are substantially similar to the allegations in her complaint, versus whether she has provided materially new information that add -- that -- whether she has provided information to the Government, in advance of her case, that materially adds to the prior public disclosures because they're two separate inquiries. She kind of tends to put the two of them together. And she's leading the Court down a path that's legally incorrect by doing so.

First, with respect to the substantial similarity. And bear with me for just a moment. A question whether two

complaints are substantially similar does not involve any assessment of whether either complaint meets 9(b). The reason why the question of whether a relator's theories are substantially similar to what's been publicly disclosed doesn't involve any 9(b) analysis is because public disclosures are not limited, in any way, shape, or form, to complaints.

And so the notion that, somehow, if -- you know, what Ms. Burke did is she sort of very neatly went through and, on the fly, argued that three of the five complaints that we are arguing would serve as a public disclosure don't meet 9(b), so you can sort of put them aside, and the only ones we need to deal with as potential public disclosures, notwithstanding all the statutory arguments, are Burns and Doe because they have some 9(b) details. So now let's focus on those, and start talking about original source.

So what she's trying to do there is argue that, somehow, the False Claims Act imports into the evaluation of whether a public disclosure is substantially similar to a relator's allegations an analysis of whether the public disclosure meets 9(b). And there is -- that's nowhere present because most public disclosures, if you look at the various categories that are allowed to be a public disclosure in the statute, are not the sort of things that you would ever apply Rule 9(b) to. And so that project is just, full

stop, legally wrong. It's precluded by -- it would be a gross error.

And she, notably, is citing no case, zero, for the proposition that that is the analysis that you should apply here. She is inventing it out of whole cloth, and it's certainly not in Moore, which I am trying to get my fingers on right now because we will talk about it in a second.

But for starters, with respect to whether the two complaints are substantially similar, you do not look at 9(b). The -- sorry. Why can't I put my hands on Moore? If you can bear with me for just one moment, Your Honor.

THE COURT: Certainly, Counselor.

MS. MAYER: Oh, it's right in front of me. That always happens, right?

In Moore, the Third Circuit first addressed whether the fraud alleged by the plaintiff was publicly disclosed. Okay? And they said the first thing we do is consider whether the sources on which defendants rely in arguing that the fraud was publicly disclosed qualify as disclosure sources. We've talked about that, and we'll come back to that later. And then we next determine whether substantially the same allegations or transactions were publicly disclosed through these qualifying sources.

(Pause in proceedings)

MS. MAYER: And the way the Third Circuit says you

go about that analysis is you say -- that you ask whether the allegation of fraud, which would be -- and again, Moore says (z) [sic] -- is factually described sufficiently in the body of the public disclosures, through, for example, saying, if you're relying on various transactions to demonstrate that fraud. And the fraud alleged here was that, under a treaty that required U.S. ownership of vessels, the defendants had created a situation where they had fraudulently enabled foreign ownership of the vessels, while representing to the Government that -- the U.S. Government, to get these licenses, that they were -- these were U.S.-owned. So that's the fraud alleged by the relator.

And so the question is: Did the prior public -- as the Court is analyzing this -- and this is at -- I'm trying to find the page cite for you -- 303. So it's 812 F.3d, at 303.

So the first thing, when you have a situation like this, where -- and again, these -- nobody was alleging that the -- that fraud theory was present in any public disclosure, but just that the facts that reveal the fraud were disclosed in that prior public disclosure. The Court says, okay, so now we look at the facts in the public disclosures.

Well, in the news media, there was information about the vessel captain being American, but not having

control of his vessel. And in the FOIA reports, we had information about representing to the Government, by the owners, that this was a U.S.-controlled vessel. So we have a disconnect there that gives rise to that inference of fraud that is the theory that is alleged.

In this discussion of substantial similarity, which concludes before the Court turns to original source, there is no discussion of whether 9(b) details are alleged or present it the public disclosure. It's simply not a part of the analysis. The Court eventually talks about 9(b), and we'll talk about that in a second. But for purposes of evaluating whether the public disclosures that Medtronic has put forth in the summary judgment argument and in its papers are substantially the same as the allegations in Ms. Forney's complaint, the question is just whether the facts alleged in those complaints reveal the theory of fraud that she is propounding in her case.

We believe they actually propound that theory of fraud. But the whole point is they just have to plead and reveal those facts in this public forum, and they more than do. And so there's no 9(b) analysis. The fact that she has pled what she -- in her second amended complaint, which she claims to be more specific details on certain respects, and that the lean sigma brand was revealed, is irrelevant to the substantial similarity analysis, provided her theory that

consulting services, practice management consulting, and device checks were -- that's her theory, device checks were provided for free, and that was a kickback to doctors, and Medtronic did it to sell product. That's in every -- that's in Onwezen and Doe and Burns and -- not Schroeder.

But we believe facts supporting that are in Stokes; not the whole theory, but facts supporting it, that Medtronic fields sales were, as a routine matter, going out and, widespread, across the country, going to specific hospitals, doing device checks and interrogations and reprogramming as a fact. That, in and of itself, isn't -- is not enough to preview Ms. Forney's fraud, but that, when added to the other disclosures, adds a little bit to it, including specific examples of hospitals and regions in the country where this was going on. So that's the substantially similar test.

So her argument that you should somehow not consider and reject the notion that anything other than the Burns and the Doe complaints were substantially similar to her allegations because, on her view on the fly, they lack some 9(b) specificity about individualized claims, is completely incorrect under the law. And Moore provides her no support with that, and she has cited no case for that proposition, and it's not in the statute.

Next, in terms of original source analysis under Moore. Her lead argument, in her brief and today, is that

the analysis of whether Ms. Forney qualifies as an original source, and whether what she's provided to the Government materially adds to what was publicly disclosed, is that you look at the second amended complaint. And there are two fundamental errors with that.

First, you start, again, with the statute. The statute does to say, when you evaluate what information a relator provided to the Government in advance of the litigation, you should look, in the first instance, to the complaint, or that you should look at all to the relator's complaint. In fact, unless the relator provides a copy of the complaint to the Government in advance of commencing the action, the complaint itself is just that. It's allegations, but it's not a part of what the relator must provide to the Government, in order -- and what can be considered, for purposes of whether they've added material information to the Government to meet the requirements of an original source under the public disclosure bar.

Again, this is technical, but this is the way congress has set up the statute. And this requirement that the relator, to qualify as an original source, provide information to the Government in advance of the action is not a new requirement. It's phrased a little -- you know, it's part of the revision of the statute here. But it's not a new, either limit, or expansion, versus the old bar. A

relator has always been obliged to provide the Government with information in advance of commencing the action, in order to qualify as an original source, and then the information is what's critical.

Here, relator's second amended complaint wasn't created or filed with the Court until this year, which is fully two years after she commenced this action; and, therefore, her -- so the first reason why her second amended complaint cannot be considered, when you're evaluating what -- whether information she provided to the Government in advance of her commencement of the action satisfies the requirements of being an original source, is that the second amended complaint and whatever it contains -- first of all, it's just allegations, and we're at summary judgment.

More to the point, the document itself contains characterizations of documents, allegations that are untethered to documents, and frankly, some really, really troubling exaggerations and misrepresentations of documents, and contains a lot of information that Ms. Forney herself apparently doesn't have, and can't explain where it came from. That document was filed and created in 2017, and so that document is absolutely, under the plain language of the statute, barred from consideration.

Some relators do disclose, in their disclosures to the Government, in advance of filing and action, a copy of

the complaint. You will occasionally, in the case law, see reference to the relator's disclosing complaints as part of that packet. The documents that were provided to you and were identified for us don't contain a copy of even the original complaint in the case, and so the complaints are out.

I will note, just so that the Court understands, when you look at Moore, and when you look at other cases in this area, what you are seeing. Public disclosure bar is sometimes litigated at the motion to dismiss stage. When it's litigated at a motion to dismiss, there has been no discovery or effort to take discovery. It is a motion to dismiss.

Under those circumstances, what a defendant will do, if they want to raise the public disclosure bar at that point, is put in the public disclosures. But with respect to the relator's qualifications as an original source, unless the relator offers a declaration or some sort of voluntary supplemental information about their disclosure to the Government in advance of the litigation, all that we have on the record is what relator alleges in the complaint is their disclosure in advance of the litigation. And Courts routinely use the complaint and allegations in the complaint as a proxy for that because we're litigating the public disclosure bar in the absence of discovery, at an early

stage.

In this case, we are litigating this issue now, after discovery. And so it's no longer either necessary or appropriate to rely on a complaint because we don't have to worry about allegations about what was or wasn't in Ms. Forney's mind. We actually have, to the extent we have it, information about what she disclosed, and the limits of that, in advance. And it would be improper to expand the scope of that beyond what the statute limits the relator to, for purposes of what she has to do in advance of the litigation to potentially qualify as an original source.

So the second amended complaint is a giant red herring here. It's a completely irrelevant document, for purposes of evaluating whether Ms. Forney is an original source. And to be clear, it's relevant for assessing, you know the substantial similarity because it helps define her theories. But there's no 9(b) analysis. That's just looking for the facts in the body, collectively, of the public disclosures; facts that disclose the theories of fraud that she's alleging in the complaint. After that analysis, we go to original source. She's got to point to the information she gave to the Government in advance of the litigation, and that is not in the second amended complaint, or any of her complaints.

By way of explanation, our opening brief, we did

not -- even though we had tried, we had -- did not have the discovery that she's now provided to us in court, through this briefing process, about the documents that she says were provided to the Government in advance of filing the case. And so we relied on her testimony to say that the documents at issue are the documents that are identified in the second amended complaint because that was the best -- we thought that was the record for purposes of the issues in this case.

We thought it was reasonable to believe we had the information that there was to have on the record, having asked for it in a document request and interrogatory and a deposition. We thought that we had exhausted the reasonable avenues that we should be required to take during discovery, in order to discover a particular piece of information, of non-privileged information.

And I, as an aside, want to point out that I think Ms. Burke's suggestion that she had until the close of discovery to force us to keep coming up with yet more inventive ways to try to ask for the same information iteratively is -- shouldn't even be a speed bump in the Court's consideration of whether we did everything that we were required to do to try to elicit the Bates numbers or the identification of the actual communication that was provided to the Government.

The issues in this case were and are and remain

ripe for decision. This is not a premature motion. At the time we filed it, by the way, there was a jurisdictional issue here. Absolutely, the pre-PPACA claims are in it. It was not until our opposition briefing that they were taken out. And so this was absolutely and remains appropriate to raise to the Court, immediately.

Now, so focusing, though, on this. So we cleared up a couple of things. Number one, when evaluating whether we've got substantial similarity, we don't apply 9(b) to the publicly disclosed complaints to eliminate a bunch of them. That's error.

When you turn to whether she's an original source, all the discussion about, you know, the detail in the second amended complaint is irrelevant because that document is not a document that was disclosed to the Government in advance of Ms. Forney's commencement of the action. And that is the information that the statute requires materially add to the public disclosures in the case.

I next turn to her argument that Moore says that, when evaluating whether information materially adds to the public disclosures, the analysis that you're supposed to do is just ask whether the relator's complaint meets 9(b). So, in addition to the problem that you don't look at the relator's complaint in a case like this, where we're passed the motion to dismiss stage, and we actually have, you know -

- take, you know, something of a record of -- and it's clear that that second amended complaint was not produced to the Government in advance of filing the action, it didn't exist, the argument that, if a Court rules at a motion to dismiss that a particular relator's complaint meets 9(b), or simply decides not to dismiss the case, and allow it to proceed into discovery, as Your Honor did here, the notion that, somehow, that establishes that, to the extent there's some later public disclosure bar analysis, she automatically qualifies as an original source because her complaint survived 9(b), is both a complete misreading of Moore and an -- well, it is. It's a complete misreading of Moore, and it doesn't make any sense under the statute, either, for two reasons:

First, it's simply not what Moore said. Moore was crystal-clear -- and now I'm going to lose Moore again -- when it says that the analysis that you need to do to evaluate whether knowledge is -- materially adds to a public disclosure, is that you have to do a comparative analysis. You have to compare the information that was provided to the Government in advance of the disclosure to the public disclosure.

Rule 9(b) -- when Your Honor evaluated whether Ms. Burke's second amended complaint and first amended complaint satisfied Rule 9(b), you looked only at each of those complaints. There's no comparison to anything, let alone to

public disclosure of information that was neither before the Court, nor on the horizon, at that point, for any of the parties.

So the notion that -- you know, first off, that, somehow, Moore created a shortcut or a cheat to the analysis that needs to be done under the statute, comparing the information, to see if it materially adds to the public disclosure, is just sort of mystifying, where that came from. So, first of all, the fact that her second amended complaint went through 9(b) is both irrelevant because the second amended complaint is irrelevant. But it's also irrelevant because the Court doesn't hold that, if a complaint survives 9(b), the relator qualifies as an original source, without doing any kind of a comparison -- comparative analysis.

So let's turn to -- and those are -- they're so critical to clear this stuff up because it is technical. And if you move quickly through, sometimes you can miss stuff. So let's see what Moore says about materially adds and about 9(b), so we can understand it and put it in context.

When Moore is addressing materially adds -- which, by the way, was in 2016, and it was before the U.S. Supreme Court ruled in Escobar, which -- issued a decision in Escobar. And in Escobar, it was addressing the concept of materiality under the False Claims Act, and there, in the context of liability provisions of the False Claims Act, but

in that decision issued some important statements about what "materiality" means. I don't believe that what Moore says and what the Supreme Court said are in conflict. I believe the two can be harmonized.

And I mention the Supreme Court case because -- and we mentioned it in the briefs because I think it informs how to read Moore, and how to sort of build on Moore, as you conceive of the analysis that needs to be done here. But it is certainly relevant, and it would certainly be inappropriate to, you know, read Moore in a way that was inconsistent with Escobar.

So Moore looks, because it didn't have the benefit of the Supreme Court decision, first to a dictionary, and they choose the New Oxford, to look at "add" and the word "material."

In the Winkelman case, which we've also cited in our brief, which was a First Circuit decision, looking at how Escobar -- what Escobar had to say about materiality impacts the public disclosure bar, the Court cited Moore -- again, I think these decisions are all in harmony with each other -- and looked to Black's Law Dictionary for "materiality," instead of the Oxford New English, but it's the same concept, is you look at what these words mean.

And so they say it's -- you know, it's significant, it's influential, it's "essential," is another word that

comes into play in these decision. The Third Circuit says that:

"To materially add to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed" --

And then it says:

"-- so as to improve its quality."

And that gets to their definition of what "add" means, is to put something in or something else, so as to improve or alter quality. So that's the -- that's this gloss on it.

What the Supreme Court adds is a couple of things. First of all, it emphasizes that materiality, in any context in the common law and otherwise, is both a very demanding standard, this is not a low bar; and number two, when you ask whether something is material, it's about is it material to -- is it important or does it add essential facts to the recipient of the information.

So, again, I don't think this is some magic silver bullet. I'm just saying these -- this is what the discussion around materiality is. So the question is not does it, in the abstract, add to the quality of the case, which is Ms. Burke's construal of what the Court in the Third Circuit here is trying to do. I think the right way to look at this is

you have to ask whether the information that the relator disclosed to the Government, in advance of filing the action, significantly adds, you know, new, essential facts to the fraud that was publicly disclosed, in a way that's meaningful to the recipient of the information, which is the Government. So it's got to be significant and essential, from the perspective of the Government. Okay? Because they are the recipient of the public disclosure, of that information. So it's just a whose perspective is it in. It's not the world, in the abstract, but the Government.

It's also clear that it's a comparative analysis here. Again, what -- as the Court goes on, it talks about whether -- you know, it talks a little bit about the relationship between the substantial similarity standard and the materially adds standard. And it recognizes that, just because they found that some -- that to -- that the public disclosure is substantially similar to the relator's theories, that doesn't answer, it's not coextensive with has the relator's information that they provided to the Government, in advance of the action, materially added, right? That they're different because there has to be able to be a gap between the two, or the materially added information -- in theory, otherwise the materially added requirement wouldn't be meaningful. And so it said, just because we found there was substantial similarity in Moore

doesn't mean that the relator's information materially added.

So then it says, well, how do we figure out what "materially added" means in this context. And we already know that they're substantially same. And the -- that's where they use 9(b). And they don't use 9(b) to say evaluate the relator's complaint. What they do is they say -- and it's said in the context of a case where the fraud that was alleged was pretty thin in the public disclosures, and there was a huge gap.

There wasn't -- these weren't -- this wasn't a public disclosure from a corporate insider. This was a public disclosure from a couple of news media sources and some FOIA information that literally disclosed American -- like a couple of salient facts, contradictory facts. And then the whole body of the public disclosure required an inference of fraud to be knit together between the two.

The who, what, when, where, and how, the 9(b) is what the Court says, that when we're trying to figure out what are the kinds of facts that, if they're not in a public disclosure, are salient. It's who, what, when, where, how. You know, is the relator adding information on those points that's missing, and that is really essential to and significant? A demanding, high bar. Okay?

And so, in Moore, the issue there was that the relators had been able to go through civil discovery in a

wrongful death case that did not, itself, qualify as a public disclosure under the new bar, and had depositions of the principals. They had taken document discovery. And so they were able to flesh out the context, the color, the -- all the why behind what was going on. Like it wasn't just, oh, I see an American ship captain who doesn't have control, and a representation that there is control. It literally got at, through the depositions and all that evidence, disclosure of, you know, here's how the sham transactions work, here are the filial and financial relationships among the different people that affected the transaction, and also, a lot of important facts about how the companies worked, what the different corporate relationships worked, how the money interacted in between and among them.

So it was -- and those are facts that are not just general here's how we do business facts. These were facts that were directly pertinent to the -- proving that there was actual fraud going on, as opposed to, well, we're going to infer fraud from these disparate facts, but you know, is it really fraud. So, there, that was the way that analysis went.

You had a low degree, very little, by way -- roughly, pretty little, by way of the public disclosure. And so the bar for what's going to materially add is going to be a lower bar. And in this particular case, the relator,

because they had litigated this case all the way through had had access to all that discovery, was able to put in quite a bit more.

Winkelman is a great example of another case that's, again, applying that same concept of materiality here. But there, what had been publicly disclosed was higher. The theory of fraud itself had been publicly disclosed in news media. And what Winkelman says -- and it applies very much here, too -- is that, when there's more that's been disclosed, the bar for what you need to add, to add something that's significant and essential for the recipient of the information, to qualify as an original source, is going to be much higher, right?

So that's why Ms. Burke is trying very hard, of course, to exclude chunks of our public disclosure because, if the only things that count as public disclosure is, you know, three paragraphs from the Burns complaint, she's got a much lower bar to meet, to try to argue that her clients -- the information her client provided to the Government in advance of filing the case, you know, might qualify as a public disclosure.

But when you look at the -- all the public disclosures as a whole, you see, you know, an extensive -- you see, on the device check theory -- you know, start there -- allegations that Medtronic's business was to have field

employees doing device checks, on demand.

Onwezen alleges that the business model was that, if you implant our device, we will do everything, from then on, for you, it's ours, we got it covered. That's the device checks, the interrogatories, it's billing information, it's everything. Talk about practice management consulting?

It's -- there are allegations in the prior-filed complaints that we had a promotional product that was a heart failure clinic in a box, where we'll give you the forms, we'll show you how to do it better, we'll do all of this. This is in the prior-filed stuff. Branded lean sigma, no, but it's the same exact kind of things that she describes.

And so, when you have this, and you're trying to figure out whether what she's disclosed to the Government materially adds, you have to ask, in light of the body of all of this, are the additional facts that are contained in those disclosures essential.

So let's turn of some of what she highlights here. Again, I maintain, and I've made -- and I don't think I need to reargue, you know, the issues about lack of admissibility around the evidence of the date and content of the information provided to the Government in advance of the disclosures, but we've already covered that.

In terms of what she's saying, aside from the complaint -- which, again, is not -- doesn't qualify as

information provided to the Government in advance -- she pointed to -- she listed that, in the information, in the documents that they gave the Government, she said there was substantial additional detail on value sales, practice management, the names of CSs involved in the fraud. There were value selling pamphlets, strategic planning documents, and a bunch of other things.

She only actually provided Bates ranges for a couple of these. So, again, I mean, this is -- we're even at oral argument, and we're getting descriptions, and we're not actually even getting what's specifically in here that's -- that matters or that's difference. But let's take on some of these things that she's identified, just to give you a sense of what needs to be done.

With respect to the value selling instruction pamphlets, which are 1915 to 2146, these are value-based selling roleplay workbook and pre-service reading. So these are the documents that they gave the Government. Again, if you look at the documents, what -- they don't add -- first, they don't add anything material to the fraud allegations. What they're doing is they're saying they're training people how to sell products by finding out what the recipient of your sales pitch cares about. It's like Selling 101.

This isn't a book that is teaching people how to provide free services. This is a book about teaching sales

reps how to listen to their audience and understand what matters to them, engage a doctor in a conversation, find out that, oh, gosh, it's really hard for us to, you know, get patients on snowy days; well, you know, we have a remote monitoring option that allows you to have your patients checked remotely, so that they don't have to come into the office; wow, that's really great, that might be a reason why I might choose a Medtronic product. Okay? That's value selling, that's what these are teaching people how to do. So, first of all, they don't add to the fraud.

Second of all -- and I think this is important, as well -- if you look at the dates on these documents -- now keep in mind, we're talking here about conduct March 23, 2010 forward. So Relator Forney provided to the Government -- and it's just the documents -- these value-based selling workbooks and things are dated 2006 and 2008. Full stop. So it's two years -- the latest one of these is two years prior to the time period where the conduct is at issue. Now, if Ms. Forney had given a statement to the Government contemporaneous with this, saying, hey, these workbooks were used in 2010 and 2012 and 2016, that would be one thing. But we don't have that, she didn't do that.

So the question you're asking is: Is this value-based selling stuff, on its face, information that materially adds to the allegations of fraud that we already see in the

publicly disclosed information? And the answer is no.

It's also worth noting that these -- you know, this value-based selling have some examples in roleplay where you're going to be talking about, you know, device checks and all of that, but again, fully publicly disclosed in the prior disclosures that there were people, clinical specialists, whose job at Medtronic was to go do device checks, post-implantation. That's what Onwezen alleged, my job, up to 40 a day -- or 40 a week, I mean, a high volume, that's what I did, day in and day out, right? That's all fully disclosed.

So, you know, seeing a document that says, you know, you're trained to ask good questions of your customers, to understand where they have problems that you can solve, is just basic selling stuff. It doesn't support fraud at all, let alone add to her theories. And it goes on from there.

In terms of the name -- in terms of the other document that she pointed out to, which are the Google calendars that she called out, this relates to the device check theory, at Bates Numbers 01249 to 1772, and 02252 to 2274. These are documents that she provided to the Government and relied on in drafting her original -- her first amended complaint, and then in her second amended complaint.

These documents certainly do provide information, details about efforts to schedule device checks. And then

they also provide information about -- they're sort of slightly illegible -- and that's generous -- printouts of calendar entries, with a lot of fairly indecipherable information on it. And again, what was provided to the Government was just the documents, not context.

They span a date range of, roughly, September 2011 to January 2012, so it's a short time frame. And they show that lots of -- if you take them at their face -- and again, I don't think this is necessarily evident, just on the face of the documents. But even being most generous to Ms. Burke, they show lots and lots and lots of device checks were scheduled to occur, lots and lots and lots of device checks were scheduled to occur.

The Onwezen complaint, on its own, the allegation that, hi, as a clinical specialist, our jobs are to go out and do device checks, all day, every day, these calendars don't add anything material from the perspective of the Government to that allegation. Okay? Because all these do is they show, at best, at best -- and again, on their face, I don't even think it's clear what they show. And keep in the mind, the document, and not testimony explaining the document, was provided to the Government. They show, on their face, very little.

I -- also, to the extent that Ms. Burke has emphasized that these documents meet 9(b), help meet 9(b),

are pertinent to the Medicare claims at issue in this case, which she's been pursuing, I also want to point out that -- and we mentioned it in passing in our brief -- her allegations in her second amended complaint, in Paragraph 49 in the first amended complaint that the Court insufficient to pass 9(b) because they didn't identify patients as actual Medicare patients, for whom Medicare claims were submitted. And that was essential for -- you know, to pass 9(b). And then, in her second amended complaint, she amended that paragraph, and said, oh, these are Medicare patients, and they did have claims submitted for them. All the information she is relying on to make those allegations are in here.

And we deposed Ms. Forney on it. And if you look at the documents, it is crystal-clear there is not one piece of payer information in here, and there is not one piece of claim information in here. So these documents do not show Medicare beneficiaries, Medicare payer, Medicare claims, or Medicare payment.

That -- when we say these show less to the Government than what the Burns complaint did, one of the things I mean is the Burns complaint attached many fewer examples of superbills. But number one, they were bills. And number two, at least for some of them, they actually indicated that Medicare was a payer on it. That's not -- she has nothing, not one thing in this huge stack of documents

that identifies a person for whom Medicare was a payer, and not this detail on these checks.

These documents show the Government what they already knew from the prior public disclosures. All those complaints on device checks, the device checks are being scheduled, the Medtronic people are doing them all the time, and that they're going forward. These documents, even though they are a high volume of checks, it's for a short period of time. And they don't add anything to what Onwezen alleged, what Burns alleged, and all of that because, again, they're showing that Ms. Forney is seeing the same thing, and is alleging the same thing that others have alleged, just based on her experience in Pennsylvania.

In terms of some of the other documents that you see in this giant stack, she cited to, I think Bates names [sic] 275 to 276 as documents that provide names of CSs involved in the fraud. I would draw the Court's attention to the documents Bates-numbered REL-00275 and 00276. My document, with those Bates numbers, are blank health insurance claim forms that contain no information whatsoever, and certainly no information about CS names.

And for what it's worth, this is raising, in my mind, once again, questions about the integrity of the production, about -- I mean, maybe Ms. Burke just miscited a document in oral argument, which is fine. But we've only

gotten pointed now, on the fly, to maybe four different jump cites within her documents, and one of them doesn't line up with her description. So, either your documents match mine, or mine match hers, or I'm not even sure who has what at this point, which, again, is -- I realize we moved for summary judgment on this jurisdictional and other issue before summary judgment ended. But we had asked 16 times until Tuesday for exactly her communications with the Government. And now I'm wondering whether we even still have them.

Other documents in here -- and this is what I mean by they don't materially add to the broad public disclosure that's already there. There are no emails in this stack of documents, just by way of example. When you think about the kind of documents that a corporate insider could potentially pull and provide to the Government to really provide meaningful, essential, new evidence of fraud, that maybe the Government had only seen disclosed before in prior public disclosures at a higher level: Emails; internal corporate planning documents that talk about, we got to provide these free services, here's the ROI for the free services that we're going to be providing, right? Those kind of documents that sometimes appear in cases. None of that is in here.

What you have are, you know -- just looking at the first document, we have a PowerPoint presentation about 2009 CPT codes for device monitoring. It opens with a disclaimer

that the sources for this are AMA-published and Federal-Register-published information, and you shouldn't rely on our coding advice, you should really, you know, rely on your own coders, but this is sort of for your information because we want you to have this coding information about our products. This program has the prior approval of the American Academy of Professional Coders and AHIMA. And then it goes through codes, and it's coding information.

In the prior public disclosures are disclosures about providing coding and billing information and education to doctors. Stokes alleges it in the case. It's a fact, not a fraud theory. But it's a publicly disclosed fact that he is a health economics guy and was going around teaching hospitals about coding and billing and how to do all this stuff.

Then there's a whole chunk of this material are just documents that are hospital outpatient services lab sheets, reimbursement and billing advice, again, coding information. We've got a copy of the AdvaMed Code, we've got a copy of the CMS Avoiding Medicare Fraud and Abuse Roadmap for Physicians. Providing this information to the Government doesn't materially add essential, significant information about the fraud that she is pursuing in her case, relative to these five complaints, public disclosures articulating what's going on. Most of it isn't even relevant.

She's got completely inexplicable composite documents in here, again, showing process flow at a couple examples of practices in the East Reading area. And I'm looking at REL-00471, for example. There's nothing in here that talks about Medtronic providing services for free, and there's nothing in here that talks about Medtronic providing device checks for free. It's just not -- there's nothing on the face of the document that is germane to the theories in her case.

Could Ms. Forney provide testimony about this that would potentially explain that this is a document that somehow does provide evidence that supports her theories? Maybe. But she didn't provide it to the Government in advance of filing her case, and we have no evidence that she provided it to the Government at all.

We do know she was interviewed by the Government, but both the Government and Ms. Burke are retaining privilege over that. And so you can't assume that Ms. Forney explained these documents and why they support evidence of fraud, when they don't, on their face, even relate to her theories because, to the extent any such disclosure even was made, it's either privileged or not in advance of the case being filed, as it needs to be, in order to qualify her as a relator.

There are -- there is a PowerPoint in here -- I

mean, just by way of example, you know, part of what matters, too, is there is stuff in here that just seems wholly irrelevant. There's a document here, REL-00522, called "Quality at the Roots, Ensuring Quality from Idea to Explant." It's a PowerPoint that is talking about reliability data relating to recalls. There is no theory in this case that relates to recalls and reliability of product, right? But this was part of the disclosures to the Government.

There is a document deciphering the code, which is an instruction manual on the AdvaMed Code, which she mentions in her complaint. But it is something that the Government may not have had already, except for the fact that it's already been disclosed because it was talked about in the Burns complaint. Burns alleged -- Burns describes deciphering the code in his complaint. So the fact that they are providing a copy of it doesn't add anything to what's already been prior publicly disclosed. And all it is, is an industry guidance on AdvaMed.

Again, this doesn't add anything. This isn't a significant, essential, new piece of information that adds materially to this body of public disclosure about the fraud alleged, which is you are providing device checks for free, in order to get remuneration.

You certainly see, you know, an agenda about a

clinical specialist annual meeting that says, hey, we want you guys to contribute to profitability. Okay. But that's it, right? No explanation. This is not a document that adds to the Onwezen and other allegations, that say, my job was to go do device checks for free, to make sure the doctors knew that, once they implanted our product, we would take care of everything for them, from that point forward, right?

There are, you know, some compliance policy pieces of information here that say Medtronic has a compliance policy. It doesn't add anything that's essential, that's demanding, that's significantly new to all of the prior disclosure. Again, it doesn't even talk about the fraud, and there's no context and no connection drawn.

The last type of document that I'll sort of talk about here -- but it's really -- these are just -- they don't do what she says they do. You know, they certainly have some documents that talk about, here's what we expect from a clinical specialist, here's what we expect from a manager of clinical specialists. Those documents in order to be compensated, in order to be promoted say, you are expected to do device checks, to proactively reach out to customers, and make sure they're being taken care of, to add value. Okay?

That doesn't add anything materially new to the already existing body of allegations about Medtronic reps going out and doing free device checks, in order to sell

product. This just says, in fact, your job is defined, in part, as going out and doing device checks, and we want you to add value; i.e., we want you to sell the product. It's just giving the Government the same information that it already has because those definitions of the position are not connected to -- it's not a performance review of an individual who's being disciplined for, you know, you are doing -- are refusing to do free device checks, you know, I'm going to discipline you and demote you or something like that. And I'm just making stuff up because there's nothing like that.

That's the kind of new information; the who, what, where, how information that Moore was talking about, and that was available in Moore because of the discovery that had been taking place, the depositions, the document discovery of the defendant. There is nothing here that does that.

She mentioned, you know, strategic planning documents. Yeah, there's a document about how to do a strategic plan. There's, you know, documents about how to handle recalls. There's a HIPAA privacy fundamental, and there's no HIPAA claim in this case. Again, there's sort of healthcare economics information that just -- none of this is about -- is pertinent to or adds materially to what the fraud is. None of it contains individual employee information or connections between employees and managers, instructing them

to perform fraud, instructing them to do the kind of stuff that's at issue here.

So, even if the Court considers this sort of giant set of documents that the relator has produced, kind of at the eleventh hour, there is nothing in there that materially adds to the public disclosures, and to the extent that this is what was provided to the Government in advance of filing the action.

I wanted to just wrap up because I know I've been going for a long time. If I might just address a couple of Ms. Burke's points about the first part of this, which is qualifying for the statute. First, she pulled Stevens out and read from it, and argued that the holding in Stevens is a rejection of the notion that the relator serves as an agent of the Government. And I think I read, actually, the same parts of the decision, too.

The issue is not whether the Court held that, for purposes of the bounty piece, the relator is a partial assignee of the Government's right to recovery. I think I acknowledged that, I said it's part of the holding. The question is: What about the rest?

And the way the Court tees it up is that the Court says -- I'm on it -- where the Court says:

"It would perhaps suffice it to say that the relator is simply the statutorily designated agent

in whose name, as the statute provides, the suit is brought, and that the bounty is simply the fee, that would take care of things, but that analysis is precluded by the fact that the relator himself has an interest."

I want to point the Court to the modifier on the "simply." The Court is saying maybe it would be -- it would perhaps, in theory, suffice it to say that there's a simple answer here, across the board, the relator is an agent because the statute designates him an agent. But what the Court is saying is it's not that simple, it's a little bit more complicated, and we have to deal with the bounty portion. And that's why, at the end of that paragraph, after the Court explains why that simple answer, to cover the entirety of standing, doesn't work. The Court says:

"For the portion of the recovery retained by the relator, therefore, some explanation of standing other than agency must be identified."

And then goes on to say, again:

"There can be no doubt, of course, that, as to this portion of the recovery, the bounty he will receive, he has a concrete private interest."

And then the Court goes on to talk about:

"However, we believe that an adequate basis for the relator's suit for his bounty is to be found in the

doctrine of an assignee of a claim and the partial assignment of right, and therefore, that the U.S. injury, in fact, suffices to confer standing on Relator Stevens."

So what the Court is quite explicitly doing is saying, yeah, the statute designates you the agent, but our inquiry doesn't stop there. That's what's being rejected here. You've got this bounty that you have an independent right to sue for. And for that, and that portion, we need another answer, and we like the answer which is that you're a partial assignee of rights, which is entirely consistent with Footnote 4 and everything else she said. And so the Court is saying this is a little bit more complicated.

And we cited a Fifth Circuit case, which is after Stevens, which recognizes this is not a big deal because this issue that we're really -- you know, just sort of cut away because the Supreme Court had resolved the issue. But there's a Fifth Circuit decision which sort of acknowledges, again, this sort of split issue that the relator is an agent, and the relator is an assignee for purposes of the bounty in a footnote in that decision, and it's cited in our brief.

So, again, I just -- this case, I think just the plain language and the logic of what the Supreme Court said in Vermont Agency supports the fact that the relator -- I mean, they're statutorily -- they're a statutorily designated

agent. This is all consistent with the structure of the state. The U.S. remains a real party-in-interest.

Of course, if the relator litigates the case, it ends up binding the United States across the board because, if Ms. Burke, you know, goes to trial and loses, the United States can't come in and say, oh, and now we want to relitigate our 70 percent sure. So of course the United States is bound the same way a principal is bound by the agent, by the relator's actions.

And in fact, the fact that the United States retains a lot of rights, even when they don't intervene, including the right to ask for copies of all the pleadings, to supervise, to participate, if it elects, and not to, if it doesn't, to monitors, required to be informed of the proceedings, and can intervene for good cause shown at any time is also indicative of the fact that they're a principal who retains some degree of control over their agent. The agent certainly has the right to litigate the action, when the Government doesn't intervene, and with respect to the relator's bounty, has some special rights with respect to Government objection to settlements and things like that, which are -- the Supreme Court recognized. But none of that changes the fact that there's an agency relationship that covers the rest of the case, and so -- that's designated by statute.

With respect to the argument that the Gadbois case somehow is inapposite and doesn't hold on the point that, when the Government intervenes in an action, they become a party to the action, Gadbois is an example. It cites Eisenstein for the proposition, when the Government -- which is a Supreme Court case from the 2009 -- when the Government intervenes in an action, it intervenes in an action; when it doesn't, it's not a party.

You know, look, the plain language of the statute says "intervene in the action." It doesn't say you intervene in the claim. Her argument that the DOJ has somehow modified through some sort of -- by its practice, whether longstanding or not, of filing papers when it's choosing to settle a case by saying that it's intervening in some, and not in others, and that Courts acquiesce to that, doesn't change the language of the statute or the status of DOJ.

I think any litigant would be free to argue that, even when DOJ files that, the DOJ becomes a party to the action. There's -- no court has ever disagreed with the proposition that I'm advancing to you, and Gadbois agrees. It says you become a party to the action when you intervene. There's just -- you can't -- DOJ can't, by fiat, with filings, just invent some new limitation that doesn't apply.

Plus, this is the normal way things work, which is -- in civil litigation, which is, if a party is only in a few

claims in a case, and not all of them, they're still a party to the case, right? That doesn't mean that somebody can sue them on claims that haven't been asserted against them. Fine, it doesn't mean anything. It just means -- but it still means that they're a party to the case.

If you've got three plaintiffs, right? And two of the plaintiffs are pursuing two of the claims, and one of the plaintiffs is pursuing, you know, a different two claims, they're all still parties to the case. So it's -- I think it's really important here to recognize that, first of all and foremost -- and it really ends the question -- the False Claims Act itself says that, when the Government intervenes, they intervene in the action. Full stop. That ends the inquiry. There is no case that says otherwise, and there is no reason that's been given to suggest otherwise, other than DOJ's practice in filing documents, which has never been critically reviewed by a court, except to the extent you're starting to see it be critically reviewed by Courts like Gadbois, and the Courts are rejecting it. And Ms. Burke hasn't pointed to any court that's accepted it at face value, where it's been contested.

And then second, again, in normal civil litigation, when you're either a party or not a party, whether you're in all or some of the claims of the case. And so we believe that that's consistent, as well. So the Government is a

party to two cases. The relator is an agent of the Government with respect to all three, for purposes of the public disclosure bar.

With respect to substantial similarity, it's the last issue. I think I address the principled concern with Ms. Burke's argument, that, somehow, most of these complaints should be ignored because they weren't pled with 9(b) specificity.

I think the only other thing I would say is I do think, if the Court has any questions or hesitation about whether the paragraphs we've presented do show that they're substantially similar, this is not a high-bar test, whether they're substantially similar under the Court's -- you know, the much more fact-intensive test is the one under the original source question, which is: Given all the public disclosures, does the information that she provided to the Government in advance of the case materially add to the body of what was publicly disclosed.

But there is no requirement that the public disclosures themselves have any particular level of detail. They just need to disclose, as a general matter, the fraud that's alleged in the complaint. And here, we think they more than do.

THE COURT: Very well, Counselor.

Any final word, Attorney Burke? You two, you don't

seem to agree on anything.

MS. BURKE: Your Honor, I'll be brief, but I think there are a couple of important points to make; first, about whether or not a relator is an agent.

There is a 2009 case that's after the Stevens case. And in that case, it held that, when the United States declines, it's no longer a party. It's impossible to reconcile that later Supreme Court holding with the manner in which Medtronic reads the Stevens case. On the other hand, if you read the Stevens case and look at what the Court actually held, what the Court held was that the relator was a partial assignee. That holding is, in fact, then consistent with the later Supreme Court ruling and --

THE COURT: Yeah, but the problem with that is, if a statute says "the Government or its agent," who could it be talking about? Who else would be an agent in this type of case, except the relator?

MS. BURKE: Well, Your Honor, the term "the Government or its agent" is used elsewhere in the statute. And what it's talking about is, for example, Centers for Medicare and Medicaid. They are referred to as an "agent of the Government," so --

THE COURT: Isn't that considered the Government.

MS. MAYER: No, it --

MS. BURKE: No, it's considered an agent because it

says, if you file a claim on the Government or its agent. So they are -- in that context, they're considered an agent.

THE COURT: So you think the "Government" means just you have to file a claim against the United States Government or the United States Government, and any agency of the United States Government would not be the United States Government?

MS. BURKE: So -- well, for example, it says the phrase "in which the Government or its agent is a party." So, for example, if there was a case that wasn't -- it wasn't a *qui tam*, but it was simply a lawsuit, and it was a lawsuit against the Centers for Medicare and Medicaid, and that was the named party. That would qualify under this as something that constituted a statutorily eligible public disclosure.

THE COURT: The Center --

MS. BURKE: So it's --

THE COURT: -- for Disease Control is an agent of the United States Government?

MS. BURKE: Yeah, the -- it -- yes, the -- it's an agent, it's an agency of the Government. So you're thinking of it as this is talking only about *qui tam* litigation. It's not. It's talking about all civil litigation.

So it used to be the case that a defendant, such as Medtronic, would scour all lawsuits, among -- even amongst private parties. So Congress, when it amended it, says,

okay, wait a minute, this has gotten -- this has tipped the balance too far, we didn't want it to be so easy for defendants to get away from these *qui tam* lawsuits, so we're going to -- we're going to reign back in and shrink that pool of statutory-eligible lawsuits, and we're going to shrink it down to lawsuits that involve a -- they can involve a private party, but the Government or its agent has to be one of the parties.

So, for example, if, you know, the Town of Easton sued the Federal Government and, through that lawsuit, all sorts of facts came out that were pertinent, that would be an eligible public disclosure because the Government or its agent was a party. So you can't think of this just as talking only about *qui tam* lawsuits; it's not. It's all civil lawsuits.

And I would suggest the fact that -- I mean, I view the -- and I apologize. I do not know the Latin phrase that captures this, but of statutory interpretation. But "relator" is a term of art used in the statute. If Congress wanted to subsume declined *qui tams* into this category, and Congress, obviously, is put on notice that the relator has been held not to be an agent, but is held to be a partial assignee, and the -- Congress is, obviously, put on notice with the 2009 case of the Supreme Court that the United States is not -- even if the relator pursues it, the United

States is not considered a party. Now, if the relator was an agent, then the U.S., by definition, would be a party.

So, given that -- given the Supreme Court holdings, if Congress wanted to make sure it subsumed declined *qui tams* into this -- you know, into this statutorily eligible bucket, it would have used the term "relator." So I think that there's no way you can read the two Supreme Court decisions that preceded the congressional change the way that Medtronic is urging. I think it's counter to the -- it's counter to that 2009, the Einstein [sic] decision, 556 U.S. 928. It basically makes that -- it basically ignores the impact of that because that could -- you could not reach a decision that the United States is not a party if you deemed relators to be their agents.

So I think -- I just think we're right on the law on that one, Your Honor. And for that reason, I think that these need to be dismissed as having not identified sufficient public disclosures.

I'll speak briefly to the Gadbois case, simply just to point out what I said about it. That case doesn't have a partial intervention, partial declination. It's got two different lawsuits. One intervened; one declined. So, therefore, it doesn't shed any light on what's before Your Honor, which is one of these partial interventions, partial -- and as a practical matter, there hasn't been litigation

about this. The Courts have gone along with it.

And in the particular case that we're dealing with, the Onwezen and Schroeder case, the Court entered that order. It could have rejected that and said, you're either in or you're out. It didn't do that. It went along with that approach. And so I would suggest there's no reason for Your Honor not to go along with that approach, as well.

Importantly, I want to turn to the way in which Medtronic tries to get Your Honor to ignore the second amended complaint, and also suggest that, somehow, we haven't introduced admissible evidence because -- through -- that, instead, it was just hearsay. That's simply wrong. The -- we put in an affidavit, we put in a declaration from Forney as Exhibit 16, in which she says, at Paragraph 5:

"Through my counsel, I am providing the Court with a Bates-stamped copy of the documents that my counsel provided to the Government in June 2015. The documents provided to the Government were not Bates-stamped, but otherwise, the documents are the same. My counsel has marked this copy as marked Relator's Exhibit 18."

That's direct knowledge. She knows that. That's what was done. These documents that we gave you and had given to Medtronic were given to the Government.

The other thing I would point out, and the reason

that I just suggest you look to the second amended complaint, the second amended complaint, she testified in her deposition that everything in the second amended complaint was given to the Government. So it's simply a way for Your Honor to look at the documents, to look -- and they're quoted at length in the second amended complaint. And the testimony there is at Forney 255 to 56.

So the suggestion that, somehow, at this -- that, halfway through discovery, you're supposed to simply accept all of Medtronic's allegations that these documents are meaningless to prove the fraud, and ignore our claims, that, in fact, we are relying on these documents, and they will prove the fraud. It -- you're -- it's not at a point where you're permitted to do that. I mean, under Celotex and the others, discovery hasn't closed. We still get the benefit -- we get the benefit of the assumption that that is fraud.

All of Medtronic's arguments, basically, are the same arguments they use to argue there's no fraud. They characterize all -- they characterize everything we've put forward as novel, immaterial, not proving any kind of fraud. They simply dispute the entirety of the case.

Well, when you look at it from our point of view, we believe it's a strong fraud case. We believe that sending people out, incenting clinical specialists and sales reps to get out there and give free services; services that are then

billed to the Government, services that are not paid for, services that are not paid for by the physicians, that is a kickback.

And so, when you look at it from our perspective, all of the documents that we gave you, and all the documents we gave the Government are material. And they will be used to show the jury all of these people were financially incented to believe in this -- to behave this way. And it worked.

I mean, it worked even on Relator Forney. I mean, you know, she did it. And she supervised other people, instructed other people to do it. The documents go to how they were trained to do it, it goes to the implementation. It goes to all of the specific details.

And on that, I would suggest, Your Honor, that you just look at the language of the Moore case. Medtronic tries to claim, okay, well, you know, that somehow I'm ignoring the remainder of the public disclosures, except for the 9(b) elements. Not at all. Those complaints, you can trudge through them, as I did, you can read them in their entirety. What I gave you were the high points. I gave you their most specific, their most detailed allegations because those are the most powerful, right?

The most powerful information is found in the Burns complaint and in the Doe complaint. And they've got actual

transactions, actual fraudulent transactions that they identify. And those have power, and those have merit, and they are very similar to what we have. But we have more, and we have different, and we have -- and we also have a completely different kickback scheme with the lead sigma.

So, when you look at Moore, which is really the case that's going to guide your analysis, it doesn't say, try to put yourself in the shoes of the Government and make a very stringent determination on materiality, not at all. What it says is look at what is out there in the public, look at it -- look at it in the public, and then look at Rule 9(b) to see whether anything new has been added. And so it reads, you know:

> "Rule 9(b)'s pleading requirement is of some assistance."
>
> And it talks about 9(b). And then it says:
>
> "In our view, this standard also serves as a helpful benchmark for measuring 'materially adds.' Specifically, a relator materially adds to the publicly disclosed allegation or transaction of fraud when it contributes information -- distinct from what was publicly exposed -- that adds in a significant way to the essential factual background; the who, what, when, where, and how of the events at issue."

Measured by that standard, it is impossible to rule for Medtronic. We have definitely added substantially to the factual background. They've got some good facts that they've alleged; we have way more. And we have a voluminous amount in the calendars that we have given to Your Honor. So we have that -- we pass that bar. And that is what the Third Circuit says is the bar of "materially adds."

And we think the reason then Medtronic is fighting so hard to claim you shouldn't look at the second amended complaint, and you shouldn't actually look at the documents, and kind of mocking the import of the documents, is because it's pretty clear we pass that Third Circuit test. I mean, we have provided to the Government a substantial amount of additional factual information. We've given them names, we've given them dates, we've given them details on how it is done.

And so, Your Honor, we think that this motion for summary judgment should be denied, and that the case should resume discovery. Thank you, Your Honor.

THE COURT: Thank you very much, Counselor.

MS. MAYER: Your Honor, may I just address --

THE COURT: Sure.

MS. MAYER: -- two --

THE COURT: A final word?

MS. MAYER: -- two small points, Your Honor?

THE COURT: Sure.

MS. MAYER: First, with respect to the agency issue, Ms. Burke is arguing that -- is conflating two terms, which mean very different things. An "agency" is not an "agent," they're different. CMS is an agency, DEA is an agency. There are places in the False Claims Act that talk about aspects of the act that apply to officers or agencies of the United States. That's distinct from whether the Government or an agent is acting.

Second, is that provision meaningless? Because -- I'm going to take her at her word. Because I've almost, but not quite, memorized the False Claims Act. That -- there's provisions that say, if you make payment to the Government or an "agent," as opposed to "agency." I'm assuming it says "agent" for purposes of this discussion.

The Government sometimes contract out, they use physical intermediaries to collect money. Like there could be a private entity that the Government has contracted with to collect funds, a granting institutions that's doing grants with federal funds. And if you make a false claim to an agent -- to someone who is either an agent or a contracted delegatee [sic] of authority from the Government, there is a way for this to make perfect sense without it being coextensive with federal agencies, which is how Ms. Burke would have you read the term "agent."

Finally, Eisenstein doesn't support Ms. Burke's position that an agent -- that, when it -- when the statute says "the Government or its agent," it means the Government, and nothing else. In particular, she said Eisenstein makes no sense because it holds that, in an non-intervened case, the Government is not a party, and it couldn't be the case that, if its agent satisfied this requirement, that would make the Government a party. And that's not the case.

Eisenstein doesn't talk about agents in that term, but Eisenstein talks about what it means to be a real party-in-interest. Okay? And it says:

> "The phrase 'real party-in-interest' is a term of art used in federal law to refer to an actor with a substantive right, whose interest may be represented in litigation by another."

And it refers to Federal Rule 17(a). And FRCP 17(a) lists different types of examples, they're non-exclusive, of where a real party-in-interest may have delegated authority to someone to act in their interest for a certain purpose, and one of those examples is designated by statute. So that's all that we're talking about here, not for the part of the bounty where the rationale for relator standing, according to Vermont Natural Resources, is that they're a partial assignee in the Government's right.

And for the rest of it, where the Government

remains a real party-in-interest, and is a real party-in-interest, the False Claims Act has delegated to relators the authority to sue on behalf of the United States, as well as the relator suing on their own behalf. And that's just sort of the run-of-the-mill, same kind of agency that Stevens recognized and that is recognized in Eisenstein in a different context.

Finally, with -- I mean, if it matters to the Court, in the Gadbois case, if you read, you know, three sentences down, the Court does talk about, after going through its analysis of the statute and the plain meaning of the statute, it goes down and does some additional analysis about the Court is concluding that the functional result of a Government complaint is to amend the pleading. And it concludes -- and I'm looking -- by saying:

> "This means that the Government became a party to Mrs. Denk's whole action, every allegation, every cause of action, even if it elected only to proceed with and ultimately settle the claims related to controlled Schedule II drugs."

I understand that Ms. Burke wants to say that, somehow, if, *ab initio*, you say up front, I'm only going to intervene in part of it, but the whole gist of this argument of what's going on here and of the analysis here is that the statute's plain language is plain, that you intervene in an

action, there's no separation. It's a District of Rhode Island decision. It is not binding, in any way, on this Court. It's only useful to the extent it's persuasive, and that's the spirit in which it's offered.

Again, you know, she has no authority that she's pointed the Court to that holds otherwise, other than a practice of U.S. Attorney's Offices that does not appear ever to have been challenged meaningfully by the Courts or both other parties, and whose import, especially in the context of whether it renders the United States a party, for purposes of something like the public disclosure bar, hasn't been addressed.

And so I, under those circumstances, respectfully suggest you default to the plain language of the statute, unless -- with respect to -- sorry, next to last. Just because she mentioned in passing, if the Court has questions, I want to address them.

She said that, because we filed a motion for summary judgment before discovery concluded, that somehow, under Celotex, she is entitled to the benefit of an assumption that she has shown fraud or is showing fraud, or something along those lines.

I wanted to emphasize that you are entitled, under the rules, to ask for summary judgment at any point in time. If the relator believes that there is additional factual

material that needs to be developed, in order for this motion to be ripe for consideration, there is a provision in the rules that allows her to assert that. And if she can make a showing that there is specific additional discovery that's needed, in order to litigate the issues brought forward on summary judgment, then the Court can hold the summary judgment motion and go forward on that.

Rule 56 has been amended; I forget if it's (d) or (f) or what now, at this point. But this is -- there's a procedure, if you think summary judgment is premature, and you need additional discovery, and you're entitled to it, to take it, to do it. She didn't invoke that provision. She is not asserting that there's more discovery that she's entitled to or needs, in order to resolve the issues in the motion. I think it puts to bed whether this is a premature motion.

The second issue is with respect to what inferences or whatnot that she might or might not be entitled to. There is nothing special that she gets, in terms of inferences, just because this is a summary judgment motion that's been filed in the middle of summary judgment, versus otherwise. The standard approach applies.

We were the moving party, so it's our burden to assert a record upon which we can say there are uncontested facts that demonstrate that, to the extent we have a burden, we can carry it, and to the extent she has a burden, she

can't meet it. To the extent we do that, the burden then shifts to her to point specifically to facts that either materially place necessary facts in dispute, or that demonstrate -- to introduce new facts that demonstrate she can meet her burden. There is nothing different or unusual about what's going on here, compared to the normal summary judgment approach.

And I think we've done that. We believe we've more than carried our burden of demonstrating public disclosures that are substantially similar to the allegations of fraud that Ms. Forney alleged in her complaint. I don't believe there are any contested facts around that, only dispute about legal issues and legal consequences of what's been disclosed. The complaints say what they say. Her complaint says what it says, and those are the operative facts, for purposes of that inquiry.

When we turn to original source, we believe that, since it's something she has a choice to invoke, she needs to invoke it in the first instance; she has. We believe we did a good job why we don't believe she meets the standard. I don't believe, with the exception of -- I -- actually, I -- there's no facts in dispute around the original source, and I do want to end by pointing this out to the Judge.

We disagree about whether the information -- the legal impact, from an admissibility perspective, of what

she's offered as of record. She pointed to Ms. Forney's declaration that says, you know, I'm aware that these documents were provided. I think her deposition makes clear that she didn't have personal knowledge of those documents, and that her knowledge of the date that anything was submitted to the Government was from her counsel. Her counsel provided the Bates ranges.

Ms. Forney didn't even know if it was 1 document or 5 documents or 12 documents. She certainly didn't have personal knowledge of the Bates ranges. And that's fine, as far as it goes. I'm just saying that the way Ms. Burke has chosen to put her evidence in is it's hearsay, and it's inadmissible. So we disagree about the legal import, but not the actual underlying facts, so it's ripe for a decision on that.

In terms -- if the Court chooses to consider the documents that were submitted to the Government in advance of filing the case, and chooses to accept that this is the set of what they were, we don't have any way to dispute that that's what they were, and so that is the set that we're going forward with, as what was provided. Ms. Burke has, even through this entire argument, not pointed the Court, except in a couple of rare instances, to anything in those documents, specifically, that she believes supports her argument that they materially add to the public disclosures.

And that's where I will end because she concluded her argument by saying that she focused on Burns and Doe and the 9(b) specificity there, the individual transactions and claims, because she said that's the really good stuff. I want to close by pointing to something, if you are going to, unfortunately, spend a piece of the next part of your life going through these documents.

She has promised, at oral argument and in her brief, names and dates and all sorts of specificity about the fraudulent scheme and the fraud that happened here, and in particular the money stuff that adds to Burns and Doe and the other complaints, right? She's setting the bar, and saying it's the specificity about claims submitted to the Government payers.

She, on her device check theory in those calendar documents, which we only -- you know, which -- again, if you look at -- the Government had no testimony about them or characterization of them. What she gave the Government was just the pieces of paper you have here. Okay? That -- those don't provide -- they provide no -- very little intelligible information. To the extent they do provide it, it's about schedules and checks, no payer, no claim information. So, if claim information is the money here, it's not there in her case. And I specifically and on the record, you know -- well, okay.

When, you turn to the consulting theory -- and she's mentioned the words "lean sigma" several times. First of all, the words "lean sigma," I think, first appeared in the second amended complaint. In any event, the consulting theory is more thinly pled than the device check theory. The Court certainly did not dismiss it.

But I would like to point out that, when you're looking at these documents and you're looking for money in the documents, there is no document that shows transaction level claim or detail with respect to any consulting theory that might have. She didn't plead any documents that would show that. She didn't offer any examples of claims that resulted from some consulting kickback. It has never been a part of her allegations, which, again, are irrelevant to this inquiry, but she's emphasizing them, and it's certainly not in these documents. So she, herself, in what she submitted to the Government, on these -- what she claims is the most important type of material additional information, it's just not there. And with that, I'll conclude.

THE COURT: Counsel?

MS. BURKE: One final, Your Honor?

THE COURT: Sure.

MS. BURKE: Your Honor, I simply want to address this issue of hearsay, to make sure that Your Honor does consider the information that we provided, all of the

documents, because, obviously, that's an important evidentiary submission.

Prior to the deposition, we had no knowledge that public disclosure was going to even be an issue at all. And so, therefore, Ms. Forney had not refreshed her memory about what had happened several years ago. We, subsequently, put in a declaration, firsthand knowledge, that she, herself, knows and is able to testify to exactly what was given the -- given to the Government.

And in addition, she also testified that she met with the Government for a half a day. And she testified in the deposition itself, which I encourage you to read in full, she testified to her recollection, prior to being refreshed after the fact with the older -- you know, with the older email transmissions and the like. So this is firsthand -- this declaration is firsthand knowledge. There's no hearsay here. She would be able to come and testify to a jury what was given to the Government, what she gave to the Government, and the like. So I just wanted to make sure that Your Honor is considering the documents as part -- as an admissible submission.

Obviously, we just have to agree to disagree with Medtronic on materiality. You know, we believe there's a significant volume, a huge volume of specifics, of details, of the who, when, what, where, about the implementation of

this fraudulent scheme, that aren't found in the other complaints. And you can peruse the entirety of all of the other complaints, which I've done. And what we brought forward is nowhere in any of those; the same theories in two of them, yes, different facts. Thank you, Your Honor.

THE COURT: Very well, Counselor.

Counsel, thank you very much for your thoroughness. I appreciate all the time you've given to this. I know you went over the lunch hour here, so I hope you were able to get some food, and I hope everyone has a very safe trip home.

I will consider all your arguments here and take another look at it all and make the appropriate decision.

MS. BURKE: Thank you, Your Honor.

THE COURT: Thank you very much.

MS. MAYER: Thank you, Your Honor.

THE COURT: And have a very happy holiday season.

MS. BURKE: Thank you. You too, Your Honor.

MR. STROMBERG: You too, Your Honor.

MS. MAYER: Thank you. You too, Your Honor.

THE COURT OFFICER: All rise.

(Proceedings concluded at 1:37 p.m.)

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CERTIFICATION

I certify that the foregoing is a correct transcript from the electronic sound recording of the proceedings in the above-entitled matter to the best of my knowledge and ability.

January 18, 2018

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